S. HRG. 101-957

CONSUMER SEAFOOD SAFETY AND QUALITY ASSURANCE ACT OF 1990

HEARING

BEFORE THE

NATIONAL OCEAN POLICY STUDY

OF THE

COMMITTEE ON COMMERCE, SCIENCE, AND TRANSPORTATION
UNITED STATES SENATE

ONE HUNDRED FIRST CONGRESS

SECOND SESSION

ON

S. 2228

TO DEVELOP A COMPREHENSIVE PROGRAM TO ENSURE THE WHOLESOMENESS OF FISH AND FISH PRODUCTS INTENDED FOR HUMAN CONSUMPTION AND SOLD IN INTERSTATE COMMERCE, AND FOR OTHER PURPOSES

MAY 24, 1990

Printed for the use of the
Committee on Commerce, Science, and Transportation

U.S. GOVERNMENT PRINTING OFFICE
32-859 O WASHINGTON : 1990

S261-12.

For sale by the Superintendent of Documents, Congressional Sales Office
U.S. Government Printing Office, Washington, DC 20402

COMMITTEE ON COMMERCE, SCIENCE, AND TRANSPORTATION

ERNEST F. HOLLINGS, South Carolina, *Chairman*

DANIEL K. INOUYE, Hawaii
WENDELL H. FORD, Kentucky
J. JAMES EXON, Nebraska
ALBERT GORE, JR., Tennessee
JOHN D. ROCKEFELLER IV, West Virginia
LLOYD BENTSEN, Texas
JOHN F. KERRY, Massachusetts
JOHN B. BREAUX, Louisiana
RICHARD H. BRYAN, Nevada
CHARLES S. ROBB, Virginia

JOHN C. DANFORTH, Missouri
BOB PACKWOOD, Oregon
LARRY PRESSLER, South Dakota
TED STEVENS, Alaska
ROBERT W. KASTEN, JR., Wisconsin
JOHN McCAIN, Arizona
CONRAD BURNS, Montana
SLADE GORTON, Washington
TRENT LOTT, Mississippi

KEVIN G. CURTIN, *Chief Counsel and Staff Director*
WALTER B. MCCORMICK, JR., *Minority Chief Counsel and Staff Director*

NATIONAL OCEAN POLICY STUDY

ERNEST F. HOLLINGS, South Carolina, *Chairman*
JOHN F. KERRY, Massachusetts, *Vice Chairman*

DANIEL K. INOUYE, Hawaii
WENDELL H. FORD, Kentucky
ALBERT GORE, JR., Tennessee
LLOYD BENTSEN, Texas
JOHN B. BREAUX, Louisiana
CHARLES S. ROBB, Virginia

TED STEVENS, Alaska
JOHN C. DANFORTH, Missouri
BOB PACKWOOD, Oregon
ROBERT W. KASTEN, JR., Wisconsin
LARRY PRESSLER, South Dakota
SLADE GORTON, Washington
TRENT LOTT, Mississippi

EX OFFICIO MEMBERS

APPROPRIATIONS

ROBERT C. BYRD, West Virginia
MARK O. HATFIELD, Oregon

ARMED SERVICES

SAM NUNN, Georgia
JOHN W. WARNER, Virginia

ENERGY AND NATURAL RESOURCES

J. BENNETT JOHNSTON, Louisiana
JAMES A. McCLURE, Idaho

ENVIRONMENT AND PUBLIC WORKS

FRANK R. LAUTENBERG, New Jersey
JOHN H. CHAFEE, Rhode Island

FOREIGN RELATIONS

CLAIBORNE PELL, Rhode Island
JESSE HELMS, North Carolina

GOVERNMENTAL AFFAIRS

JOHN H. GLENN, JR., Ohio
WILLIAM V. ROTH, JR., Delaware

LABOR AND HUMAN RESOURCES

EDWARD M. KENNEDY, Massachusetts
ORRIN G. HATCH, Utah

AT LARGE MEMBERS

BROCK ADAMS, Washington
SPARK M. MATSUNAGA, Hawaii
GEORGE J. MITCHELL, Maine

WILLIAM S. COHEN, Maine
PHIL GRAMM, Texas
PETE WILSON, California

CONTENTS

Page

Opening statement by the Chairman 1
Opening statement by Senator Inouye 2
Text of S. 2228 4

LIST OF WITNESSES

Benson, James, Acting Commissioner, FDA 71
Bloom, Anne, on behalf of Public Citizen 94
    Prepared statement 96
Cohen, Hon. William S., U.S. Senator from Maine 47
Iani, John, executive director, Pacific Seafood Processors Assn 114
    Prepared statement 115
Knauss, Dr. John, Under Secretary for Oceans and Atmosphere, NOAA; accompanied by Thomas J. Billy, Deputy Director, Office of Trade and Industry Services; National Marine Fisheries Service; and James W. Brennam, Deputy General Counsel 72
    Prepared statement 74
Mitchell, Hon. George J., U.S. Senator from Maine 48
    Prepared statement 51
Moore, Ken, chairman, Interstate Shellfish Sanitation Conference 116
    Prepared statement 118
Sullivan, Hon. Louis, Secretary, HHS 63
    Questions of Senator Inouye and the answers 70

CONSUMER SEAFOOD SAFETY AND QUALITY ASSURANCE ACT OF 1990

THURSDAY, MAY 24, 1990

U.S. Senate,
National Ocean Policy Study,
Committee on Commerce, Science, and Transportation,
Washington, DC.

The Committee met, pursuant to notice, at 9:24 a.m., in room SR-253, Russell Senate Office Building, Hon. Ernest F. Hollings (chairman of the committee) presiding.

Staff members assigned to this hearing: Penny Dalton and Grant Cunningham, professional staff members; John Moran and Earl Comstock, minority staff counsels.

OPENING STATEMENT BY THE CHAIRMAN

The **Chairman**. The committee will come to order.

Good morning. This hearing has been convened by the Full Committee and the National Ocean Policy Study to examine the requirements of a national seafood safety program. As a part of the hearing, the Committee intends to take a close look at a bill I introduced in March to establish such a program—S. 2228, the Consumer Seafood Safety and Quality Assurance Act of 1990.

Over 50 bills requiring Federal inspection of seafood have been introduced since the 89th Congress. In other words, we have looked into this problem a number of times, but we haven't solved it. In recent months, both industry and consumer groups have called on Congress to re-examine seafood safety. The fishing industry is concerned over the noticeable drop in seafood consumption in 1988. This decrease followed a number of years of steady increases in seafood consumption, with an all-time high recorded in 1987. The drop in consumption has led many to conclude that consumers have lost confidence in the safety of seafood. In response, several bills have been introduced in the Senate and the House during this Congress which require the establishment of a national seafood safety program. These bills, in general, are focused on ensuring consumers that seafood is wholesome and safe to eat.

There are several factors creating the immediate concern over seafood safety. One is the contamination of our coastal waters from coastal runoff and sewage discharge. Another factor is the flood of foreign fishery products into our markets in recent years. From 1980 to 1987, imports increased by 50 percent. These imports now account for 65 percent of all the seafood eaten by U.S. consumers.

We must ensure that imports meet the same high standards that we expect of our domestic products.

At this time, it seems no one is quite sure how much of a problem we have with seafood safety, and statistics on seafood safety are simply confusing. For example, a consumer advocacy group has stated that fish and shellfish products are seven times more likely to cause illness than are poultry products. Yet, the Food and Drug Administration estimates that the risk of illness is twice as high from eating turkey as from eating any seafood. Clearly, an important first step in the process is getting a better understanding of the problem.

The next step is to determine the type and scope of the program needed. In the seafood industry, there are over 250 species harvested and processed in a number of different ways. There are an estimated 128,000 U.S. commercial vessels and more than 4,000 onshore processing and wholesale plants. In addition to the commercial industry, there are millions of recreational fishermen who catch fish for the table.

Presently, NOAA in the Department of Commerce offers voluntary fish inspection and grading programs. The programs are operated on a fee-for-service basis to provide sanitation and processing inspections and product evaluation. In addition, I understand the Food and Drug Administration is in the seafood inspection business. Each year, FDA inspects over 1,000 seafood processing facilities and tests hundreds of seafood samples. Finally, many coastal states have well-established seafood safety programs. It is estimated that states spend about $20 million annually on seafood inspection. Obviously, these state programs should be linked into any national effort.

My bill, S. 2228, is intended to establish just such a national program. It calls for the Secretary of Commerce to establish a comprehensive safety and quality assurance program for fish and fish products sold in interstate commerce. The purpose of the legislation is to ensure public safety, to minimize problems associated with eating seafood, and to encourage the acceptance of high quality U.S. products in foreign and domestic markets.

I look forward to the testimony presented here today, and I hope it will provide further information on the direction in which we should head with this issue.

I have a statement that Senator Inouye would like to have included in the record.

[The statement follows:]

OPENING STATEMENT BY SENATOR INOUYE

Mr. Chairman, as a co-sponsor of S. 2228, the "Consumer Seafood Safety and Quality Assurance Act," I appreciate your holding a hearing on this important legislation.

My specific concern with seafood safety focuses on the FDA recommendation that all fish intended for raw or rare consumption be frozen. Although the FDA issued a recommendation, I understand that state and local regulatory agencies generally adhere to such FDA recommendations. Hence, an FDA recommendation, such as this one, may have serious consequences for segments of the seafood industry.

I recently wrote to the FDA stating my concern that the FDA recommendation may damage the fresh tuna industry in Hawaii. In response, the FDA sent me a briefing paper entitled "Parasites in Fish," which cites five scientific studies and argued that:

"The cited studies clearly show that proper preparation on *all* fish to eliminate parasitic infection is an essential public health measure."

However, it appears that the FDA recommendation was not based on adequate information, but on selective interpretation of a few studies. The materials cited do seem to demonstrate a potential need to regulate Pacific salmon, but not tuna, in order to control parasitic worms. I have attached comments which sufficiently refute the arguments made in the FDA briefing paper.

The FDA letter to me also noted that Japan has the highest rate of Anisakiasis (parasite infection) in the world because Japan consumes more raw tuna than any other country. It is true that Japan has the highest rate of this particular infection in the world. It is also true that the Japanese consume more raw tuna than any other people. However, the evidence available shows that despite the large amount of tuna consumed raw in Japan, tuna is seldom linked to anisakiasis.

According to Dr. Noboru Kagei, Parasitologist, National Institute of Health, Ministry of Health and Welfare (the Japanese counterpart to the FDA), there are about 2000 occurrences per year of Anisakasis disease in Japan. Dr. Kagei found that more than 80 percent of the occurrence in Japan resulted from eating mackerel raw or raw with vinegar.

In compiled data provided by Dr. Kagei (5757 cases studied in northern, central and southern Japan), there were only five cases where tuna was reported as being a possible cause of infection. In that data, the possible rate of infection by tuna would be 0.08685 percent. Accordingly, Dr. Kagei, concluded that it is safe to eat tuna raw.

Mr. Chairman, I sincerely believe that the FDA has not made a case for freezing *all* fish that may be consumed raw or rare. The FDA position is a "shotgun" approach to the parasitic hazards in a few species of fish, principally Pacific salmon, Pacific rockfish, and herring. Tuna and other species which pose no hazard should not be treated the same as the species which do pose risks when eaten raw or rare. Implementation of such a regulation would have a devastating impact on the domestic fresh tuna industry throughout the U.S. and is completely unnecessary to protect consumers against potential health hazards. Moreover, the consumption of raw tuna is an important part of our cultural heritage in Hawaii. Such a regulation would undermine a custom that is an essential ingredient to our island lifestyle.

Mr. Chairman, I look forward to working with you and your staff to resolve this issue.

We welcome our majority leader who has been leading the way on this particular score. But first, Al, do you have an opening statement?

Senator GORE. No, that is fine.

The CHAIRMAN. How about you, John?

Senator BREAUX. No.

The CHAIRMAN. Good. We will hear from our Senator from Maine. And here is one of our NOPS members, Senator Cohen. Wonderful. I am telling you, Senator Mitchell you must carry him around with you.

Senator MITCHELL. It is quite a burden, Mr. Chairman.

Senator COHEN. He takes me to testimonials. He carries me around.

The CHAIRMAN. Very good. We welcome you to our NOPS hearing, Senator Cohen. Did you have a statement?

Senator COHEN. Just a couple of brief points.

The CHAIRMAN. Sure.

[The bill follows:]

101st CONGRESS
2d Session

S. 2228

To develop a comprehensive program to ensure the wholesomeness of fish and fish products intended for human consumption and sold in interstate commerce, and for other purposes.

IN THE SENATE OF THE UNITED STATES

March 1 (legislative day January 23), 1990

Mr. Hollings (for himself, Mr. Kerry, Mr. Stevens, and Mr. Mitchell) introduced the following bill; which was read twice and referred to the Committee on Commerce, Science, and Transportation

---

A BILL

To develop a comprehensive program to ensure the wholesomeness of fish and fish products intended for human consumption and sold in interstate commerce, and for other purposes.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SHORT TITLE

Section 1. This Act may be cited as the "Consumer Seafood Safety and Quality Assurance Act of 1990".

FINDINGS AND PURPOSES

Sec. 2. (a) Findings.—The Congress finds and declares the following:

(1) Seafood constitutes an important component of the Nation's food supply. Domestic and imported fish and fish products are consumed throughout the Nation, and are harvested and marketed by a large, diverse commercial fishing industry.

(2) Heightened awareness of the health benefits associated with seafood and greater diversity of fish products have raised consumption rates and increased the demand for wholesome, high quality seafood.

(3) The sale of fish havested from polluted waters and the sale of adulterated or misbranded fish products are injurious to the public welfare, destroy markets for wholesome and properly labeled and packaged fish and fish products, and result in injury to consumers and losses to the United States seafood industry.

(4) Existing Federal standards and systems of inspection and monitoring have failed to incorporate advances in science and food technology and are insufficient to ensure consumer safety and public confidence in the wholesomeness of fish and fish products.

(5) A significant number of consumer illnesses are caused by improper handling of fish and fish products in the home, and individuals dependent for dietary protein on fish obtained through recreational fishing are at particular risk.

(6) The Federal Government has the responsibility of ensuring the safety and quality of fish products sold in interstate commerce for consumption in the United States

(7) A comprehensive national seafood safety and quality assurance program is necessary to protect public health and to maintain the position of the United States as a leading supplier of and market for fish and fish products.

(b) PURPOSES.—It is declared to be the purposes of the Congress in this Act to—

(1) safeguard the safety of fish and fish products sold in interstate commerce to consumers;

(2) increase the health benefits of consuming seafood and enhance public confidence in the wholesomeness of fish and fish products; and

(3) promote commerce in fish and fish products by encouraging the acceptance of wholesome fish and fish products in foreign and domestic markets.

DEFINITIONS

SEC. 3. As used in this Act, unless the context requires otherwise, the term—

(1) "adulterated" means with respect to any fish or fish product that the fish or fish product—

(A) bears or contains any contaminant, but in case the contaminant is not an added substance, such fish or fish product shall not be considered adulterated if the quantity of such contaminant it bears or contains does not ordinarily render it unsafe for human consumption;

(B) has been made or derived in whole or in part from fish harvested in a growing or harvesting area that is determined to contain substances which indicate that such fish or fish product is likely to be unsafe for human consumption;

(C) is or has been contained in a package that is composed in whole or in part of any contaminant that may render such fish or fish product unsafe for human consumption;

(D) has been imported from a country which does not have a seafood safety and quality assurance program approved by the Secretary under section 9;

(E) is not in compliance with, or has not been processed in accordance with, this Act or standards and regulations promulgated under this Act; or

(F) has any valuable constituent in whole or in part omitted or abstracted therefrom; any substance substituted wholly or in part therefor; damage or inferiority concealed in any manner; or any substance added thereto or mixed or packed therewith so as to increase its bulk or weight, reduce its quality or strength, or make it appear better or of greater value than it is.

(2) "contaminant" means any substance which is hazardous to human health when ingested, and includes—

(A) such chemicals as heavy metals, pesticides, and polychlorinated biphenyls;

(B) such parasitic or microbiological organisms as nematodes, bacteria, and viruses; and

(C) such naturally occurring toxins as ciguatoxin and scombrotoxin.

(3) "fish" includes all finfish, mollusks, crustaceans, amphibians, and other forms of aquatic animal and plant life, whether from wild or cultured sources, except birds and mammals;

(4) "fish product" means any food product intended for human consumption and derived in whole or in part from fish, including unprocessed fish, except any product that—

(A) contains fish in a relatively small proportion or historically has not been considered by consumers as a product of the seafood industry, and

(B) is exempted by the Secretary from the definition of fish product under such conditions as may be prescribed to assure that the fish contained in such product is not adulterated and that such product is not represented as a fish product.

(5) "Hazard Analysis Critical Control Point method" means a system for ensuring seafood safety and quality which consists of indentification of the consumer hazards associated with fish and fish products and their processing, assessment of the severity of those hazards, determination of critical control points required to control the hazards, and establishment of monitoring procedures to determine that each critical control point is under control;

(6) "inspection" means the examination, by an authorized Federal or State agent, or any fish or fish product, or any processing facility, or of any activity involving the handling or processing of any fish or fish product, to ensure that the requirements of this Act and regulations promulgated under this Act are met;

(7) "interstate commerce" means commerce—

(A) between a place in a State and a place outside such State (including a place outside the United States);

(B) between two places in a State through another State or a place outside of the United States; or

(C) within the District of Columbia or any territory or possession of the United States.

(8) "label" means a display of written, printed, or graphic matter upon the immediate package (not including package liners) of any article;

(9) "labeling" means all labels and other written, printed, or graphic matter upon any article or any of its packages, or accompanying such article;

(10) "misbranded" means with respect to any fish or fish product that—

(A) the labeling of the fish or fish product is false or misleading in any particular;

(B) the fish or fish product is offered for sale under the name of another food;

(C) the package of the fish or fish product is so made, formed, or filled as to be misleading;

(D) any word, statement, or other information required by or under authority of this Act to appear on the label or other labeling is not prominently placed thereon with such conspicuousness (as compared with other words, statements, designs, or devices, in the labeling) and in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use; or

(E) the fish or fish product purports to be, or is represented as, a food for which a definition and standard of identity or composition has been prescribed by regulation under this Act unless—

(i) the fish or fish product conforms to such definition and standard, and

(ii) the label of the fish or fish product bears the name of the food specified in the definition and standard.

(11) "official mark" means any symbol prescribed by regulations promulgated to this Act to identify the status of any fish or fish product;

(12) "package" includes any container, box, can, tin, cloth, plastic, or other receptacle, wrapper, or cover;

(13) "person" means any individual (whether or not a citizen of the United States), any corporation, partnership, association, cooperative, or other entity (whether or not organized under the laws of any State), and any State, local, or foreign government, or any entity of such government or the Federal Government;

(14) "process" means to handle, store, prepare, produce, manufacture, preserve, pack, transport, or hold fish or fish products for eventual sale in interstate commerce to consumers, except (A) such actions when carried out by restaurants and other establishments incidental to retail sale and (B) handling, storing, holding, or transporting by any contract carrier or common carrier incidental to shipment;

(15) "processing facility" means any vessel, area or premises (including such structures, buildings, vehicles, support vessels, and equipment as are associated with that vessel, area, or premises) used for the processing of fish or fish products;

(16) "seafood" means fish products in general;

(17) "Secretary" means the Secretary of Commerce;

(18) "shellfish" means any species of oyster, clam, or mussel, either shucked or in the shell, and either fresh or frozen, or otherwise processed, or any part thereof;

(19) "State" means any State of the United States, the Commonwealth of Puerto Rico, the Commonwealth of the Northern Mariana Islands, or any other territory or commonwealth of the United States.

SEAFOOD SAFETY AND QUALITY ASSURANCE PROGRAM

SEC. 4. (a) ESTABLISHMENT OF PROGRAM.—Not later than two years after the date of enactment of this Act, the Secretary shall establish, in accordance with this Act, a comprehensive seafood safety and quality assurance program for fish and fish products sold in interstate commerce. The program shall be designed in consultation with the Secretary of Agriculture, the Secretary of Health and Human Services, the Secretary of Transportation, the heads of other appropriate Federal and State agencies, and representatives of the seafood industry and national consumer organizations. The program shall provide for—

(1) establishment and implementation of Federal seafood standards under section 5;

(2) inspection of fish and fish products under section 6;

(3) development and implementation of procedures for enforcing the program;

(4) monitoring of the water quality of growing and harvesting areas under section 7;

(5) delegation of inspection, enforcement, and monitoring authority to State governments and compensation to the States for carrying out that authority;

(6) design and implementation of a national consumer education and information program relating to

health hazards associated with the human consumption of fish and fish products; and

(7) establishment and administration of a shellfish indicator research program and other research in furtherance of the purposes of this Act.

(b) CONSISTENCY WITH ISSC GUIDELINES.—The program established under subsection (a) shall be consistent, to the maximum extent practicable, with the guidelines for the National Shellfish Sanitation Program developed by the Interstate Shellfish Sanitation Conference.

FEDERAL SEAFOOD STANDARDS

SEC. 5. (a) IN GENERAL.—The Federal seafood standards required as part of the program established under section 4 shall include standards prescribed in accordance with subsection (b), (c), (d), (e), and (f).

(b) SANITATION AND QUALITY CONTROL.—The Secretary shall prescribe standards of sanitation and quality control for the processing of fish and fish products. The standards shall include—

(1) plans of operation for each processing method that are based on the Hazard Analysis Critical Control Point method and on the results of the Model Seafood Surveillance Program carried out by the National Marine Fisheries Service of the Department of Commerce; and

(2) all applicable sanitation and good manufacturing practices established by the Secretary of Health and Human Services.

(c) CONTAMINANT LEVELS.—(1) The Secretary, after consultation with the Secretary of Health and Human Services, shall develop and prescribe standards for contaminant levels which are most likely to cause fish or fish products to be unsafe for human consumption. Such standards may include indicators, including indicator organisms, from which it may reasonably be inferred that a contaminant in the fish or fish product is likely to be present whenever the contaminant itself cannot be practicably detected.

(2) In developing the standards required under paragraph (1), the Secretary shall contract with the National Academy of Sciences to—

(A) identify the contaminants which are most commonly found in fish and fish products;

(B) identify the contaminants which are most hazardous to human health when ingested;

(C) recommend priorities, on the basis of public health significance, for the development of standards for contaminants; and

(D) prepare and submit to the Secretary within eighteen months after the date of enactment of this Act a report on the contaminants identified under subparagraphs (A) and (B) and the priorities recommended under subparagraph (C), together with a full explanation of reasons for such findings and recommendations.

(3) The Secretary shall report to the Congress annually, beginning one year after the date of completion of the report required by paragraph (2)(D), regarding the progress that, as of the date of such annual report, has been made to implement the standards required under paragraph (1). The annual report shall, among other things—

(A) describe, as of the date of such report, the research that has been conducted and the research that remains to be conducted in order to establish any of such standards that have not yet been developed;

(B) specify, with respect to each of such standards that has not yet been established, the public health significance of the failure to have established such standard;

(C) specify a timetable for the development of each such standard that has not yet been established; and

(D) estimate the costs, including the costs of research, associated with the development of each such standard.

(d) IDENTITY, QUALITY, LABELING, AND PACKAGING.—(1) The Secretary shall prescribe standards of identity and composition, minimum quality, labeling, and packaging of fish and fish products. Such standards shall build upon existing Federal regulations and shall be consistent with any applicable international standards related to fish and fish products.

(2) In developing a standard of identity, the Secretary shall define a common or usual name for a fish or fish product which fairly describes the nature of the fish or fish product or its characterizing ingredients. The common or usual name may include generic designations for fish or fish products which have similar nutritional properties or other characteristics affecting the marketing of food products.

(3) To promote commerce in fish and fish products, the Secretary may establish voluntary grading criteria for fish and fish products which exceed minimum quality standards developed pursuant to this subsection.

(4) Labeling and packaging standards shall include a requirement that each package of fish or fish product that is processed by a processing facility registered under this Act be marked, at the time the package leaves the processing facility, with—

(A) the unique code assigned by the Secretary under section 6 for the purpose of identifying the processing facility; and

(B) a label that bears or contains an official mark that is available only to processing facilities which are registered under this Act;

except that the Secretary may exempt from such requirement any processing facility if the Secretary determines that the facility is not the primary processing facility with respect to such fish or fish product and such exemption will not undermine the ability of the Secretary to ensure that standards prescribed under this Act are met.

(e) WATER QUALITY.—The Secretary, in consultation with the Administrator of the Environmental Protection Agency, the Chairman of the Interstate Shellfish Sanitation Conference, and the heads of other appropriate Federal or State agencies, shall prescribe standards for the water quality of shellfish growing and harvesting areas. Prior to issuing such standards, the Secretary shall carry out a comprehensive assessment of the effectiveness of existing Federal water quality standards and guidelines for classifying shellfish growing areas in—

(1) minimizing hazards associated with the human consumption of shellfish; and

(2) assuring an adequate supply of safe and high quality domestic shellfish.

(f) OTHER STANDARDS.—The Secretary shall prescribe such other standards as the Secretary determines are necessary to carry out the provisions of this Act.

(g) ADMINISTRATIVE PROCEDURE.—In implementing this section, the Secretary shall—

(1) consult with interested Federal agencies, representatives of affected States, and representatives of consumer organizations and the seafood industry;

(2) promulgate regulations to establish the Federal seafood standards required, and such regulations or guidelines as the Secretary determines are appropriate for applying and enforcing such standards; and

(3) review and revise such standards, regulations, and guidelines on a continuing basis, no less frequently than once every three years, to reflect changes in processing methods and related advances in science and technology.

FEDERAL INSPECTION SYSTEM

SEC. 6. (a) INSPECTION SYSTEM.—As part of the program established under section 4, the Secretary shall establish and administer a comprehensive and efficient inspection system for fish and fish products that protects the consuming public from fish and fish products that are adulterated or misbranded. Such system shall, in accordance with the Hazard Analysis Critical Control Point method—

(1) provide for the appointment and training of authorized inspection officers, and for the training of personnel involved in processing;

(2) be specifically designed to take into consideration the special characteristics of fish and fish products and of the processing of fish and fish products;

(3) be based upon the Model Seafood Surveillance Project conducted by the National Marine Fisheries Service of the Department of Commerce;

(4) provide for the registration and the inspection of processing facilities;

(5) provide for the inspection of fish and fish products and of the processing of them, at such points, in such manner, and with such frequency as the Secretary determines are necessary based on the Model Seafood Surveillance Project referred to in paragraph (3), a consideration of the nature and frequency of operations, adequacy of monitoring programs, history of compliance with this Act, and such other factors as the Secretary may determine are appropriate; and

(6) include such other inspection activities as are determined by the Secretary to be necessary for effectively carrying out the provisions of this Act.

(b) REGISTRATION.—(1) No processing facility may process any fish or fish product unless such processing facility is registered by the Secretary under this section, except as provided in paragraph (7).

(2) Application for registration under the program shall be made to the Secretary using such forms and containing such matter as the Secretary shall prescribe by regulation.

(3) The Secretary shall approve an application under this section unless, on the basis of such application and an inspection of such processing facility, the Secretary determines that the processing facility is unfit to engage in the processing of fish and fish products. If the Secretary approves such an application, the Secretary shall assign a unique code to such facility for identification purposes.

(4)(A) If the Secretary does not approve an application for registration, the Secretary shall promptly notify the applicant in writing of the disapproval and the reasons therefor.

(B) Any applicant whose application for registration has not been approved by the Secretary may at any time make another application for registration. The Secretary shall approve such application if the Secretary finds that the processing facility is no longer unfit to engage in the processing of fish and fish products.

(5) If a processing facility registered under this section fails to comply with any requirement of this Act or regulations promulgated under this Act, the Secretary may, after notice and an opportunity for a hearing—

(A) revoke the registration;

(B) suspend the registration for a period of time; or

(C) impose conditions and restrictions on the registration as the Secretary determines are necessary and appropriate.

(6)(A) The holder of a registration that has been revoked or suspended may at any time apply for reinstatement thereof. The Secretary shall immediately grant reinstatement of the registration if the Secretary finds that the processing facility is no longer unfit to engage in the processing of fish and fish products.

(B) The holder of a registration that is conditional or restricted may at any time apply for the removal of such conditions or restrictions. The Secretary shall immediately remove such conditions or restrictions if the Secretary finds that adequate measures have been taken to comply with this Act or regulations promulgated under this Act.

(7) The Secretary may exempt classes of processing facilities from such registration requirement if the Secretary determines the exemption will not undermine the ability of the Secretary to carry out the purposes of this Act.

(c) POWERS OF INSPECTION OFFICERS.—An inspection officer authorized by the Secretary to conduct inspections under this Act (including a State employee deputized under section 8(d) to conduct such inspections) may, pursuant to procedures prescribed by the Secretary, take such actions as are necessary to ensure the effectiveness of the provisions of this Act and regulations promulgated under this Act. Such actions shall include, but not be limited to—

(1) the inspection of processing facilities and related fish and fish products, packages, labeling, conditions, equipment, and records,

(2) the sampling of fish and fish products, and

(3) the detention and condemnation of adulterated and misbranded fish and fish products in accordance with subsection (e).

(d) RECORDS AND DOCUMENTATION.—Owners or operators of processing facilities registered under subsection (b) shall—

(1) maintain accurate records regarding—

(A) the fishery from which the fish or fish products originated;

(B) activities related to food safety and sanitation; and

(C) receipt, delivery, sale, movement, and disposition of fish and fish products;

(2) permit the Secretary, upon request, at reasonable times to have access to and copy any such records; and

(3) make available to the Secretary information relating to such matters as the Secretary may require.

The Secretary may prescribe such additional requirements for the records and documentation of processing facilities and other business enterprises as are necessary to carry out the purposes of this Act.

(e) PRODUCT DETENTION AND CONDEMNATION.—(1) Subject to paragraph (2), all fish and fish products found by the Secretary to be adulterated or misbranded shall be immediately segregated and, if objection is not made within forty-eight hours, condemned. If objection is made, such fish or fish products that are in perishable form may be processed to the extent necessary to prevent spoilage pending hearing and judicial review.

(2) If the Secretary determines that an adulterated or misbranded fish or fish product can, by relabeling or other action, be brought into compliance with this Act or regulations promulgated under this Act, final determination as to the condemnation of such fish or fish product may be deferred pending the performance by the owner of such fish or fish product, within a time specified by the Secretary, of such relabeling or other action as the Secretary may authorize. If after such action is performed, the Secretary determines that the fish or fish product has been brought into compliance with

this Act and regulations thereunder, the Secretary shall premit its entry into interstate commerce.

(3) Any fish or fish product condemned by the Secretary without objection, or after hearing and judicial review, shall be destroyed for human food purposes under the supervision of the Secretary.

(f) LABELING AND PACKAGE.—(1) The owner or operator of each processing facility registered under the program shall, subject to terms and conditions determined by the Secretary, submit to the Secretary, prior to use, any label or package to be used by that facility for fish or fish products. The Secretary shall review such label and package for compliance with the standards established under this Act. No such label or package may be used unless it has been approved by the Secretary.

(2)(A) The Secretary shall approve any label unless the Secretary determines that such label is false or misleading.

(B) The Secretary shall approve any package unless the Secretary determines that such package does not comply with the standards established under this Act.

(3)(A) If the Secretary does not approve any label or package, the Secretary shall promptly notify the owner or operator of the processing facility proposing such label or package in writing of the disapproval and the reasons therefor.

(B) The owner or operator whose label or package has not been approved by the Secretary may at any time propose another label or package for approval. The Secretary shall approve the revised label unless the Secretary determines that such label is false or misleading. The Secretary shall approve the revised package unless the Secretary determines that such package does not comply with the standards established under this Act.

(g) NOTICE.—Upon completion of any inspection and before leaving the processing facility, the Secretary shall give to the owner or operator of the facility a report in writing describing the results of the inspection.

(h) TRADEMARK PROTECTION.—The Secretary may apply for, secure, and maintain protection under the trademark laws of the United States and under the design, copyright, or trademark laws of a foreign country for any official mark or other mark, number, or device required by the Secretary for carrying out this Act.

MONITORING OF GROWING AND HARVESTING AREAS

SEC. 7. (a) MONITORING SYSTEM.—As part of the program established under section 4, the Secretary shall establish and maintain a comprehensive monitoring system to identify and designate geographical growing and harvesting areas from which significant quantities of fish and fish products not in compliance with this Act or regulations under this Act originate, or may be reasonably expected to originate.

(b) DESIGNATED AREAS.—The Secretary may, by regulation, prohibit or restrict the sale or other disposition in interstate commerce of any fish or fish products from an area designated under subsection (a).

(c) REVIEW.—The Secretary shall periodically review the areas designated under subsection (a) and shall withdraw or modify the designation to the extent the Secretary determines is consistent with the requirements of this section.

(d) PUBLIC NOTICE.—The Secretary shall notify the Governor of any affected State and the Chairman of any affected Regional Fishery Management Council, and to the extent practicable, shall give reasonable public notice before any action is taken under this section.

STATE INSPECTION AND MONITORING PROGRAMS

SEC. 8. (a) IN GENERAL.—The Secretary shall encourage States to continue, strengthen, or establish seafood safety and quality assurance programs at least equal to the program established under this Act.

(b) ASSISTANCE.—The Secretary may provide to a State, in the planning and developing of such a program—

(1) advisory assistance;

(2) technical and laboratory assistance and training (including necessary materials and equipment); and

(3) financial and other aid.

(c) APPROVAL OF STATE PROGRAMS.—(1) At any time after establishment of the Federal seafood safety and quality assurance program under this Act, the Governor of any State desiring to administer its own seafood safety and quality assurance program may submit to the Secretary a full and complete description of the program the State administers or proposes to establish and administer under State law. In addition, such State shall submit a statement from the attorney general (or appropriate legal officer) that the laws of such State provide adequate authority to carry out the described program. The Secretary shall approve each such submitted program for a period of no more than five years unless the Secretary determines that adequate authority and capacity does not exist to—

(A) ensure that fish and fish products originating in the State and entering interstate commerce meet or exceed the Federal standards established under section 5;

(B) ensure that inspection and monitoring systems are comparable in effectiveness to systems established by the Secretary under sections 6 and 7;

(C) provide the Secretary with regular reports regarding State activities under the program; and

(D) abate violations of the program, including civil and criminal penalties and other ways and means of enforcement.

(2) The Secretary shall monitor the effectiveness of each approved State program and if such program is not being effectively implemented shall, after notice and opportunity for hearing and appropriate corrective action, withdraw approval of the State program and reinstate the Federal program.

(3) The Secretary shall annually grant to each State with a program approved under this subsection an amount not to exceed 60 per centum of the cost of operating a federally equivalent State program.

(d) DEPUTIZATION OF STATE EMPLOYEES.—For States that are not approved by the Secretary under subsection (c), the Secretary may deputize specific State employees under an agreement with any State to carry out, on behalf of and at the request of the Secretary, inspection and monitoring activities pursuant to sections 6 and 7. Agreements with a State under this subsection may provide for training of deputized State employees. The Secretary shall pay for or reimburse the State for the expenses of such training and for the actual cost of inspection activities performed by a deputized State employee at the request of the Secretary.

IMPORTS

SEC. 9. (a) IN GENERAL.—(1) No fish or fish product may be entered, or withdrawn from warehouse, for consumption in the United States unless such fish or fish product—

(A) is not adulterated or misbranded;

(B) complies with all standards applicable to fish and fish products in interstate commerce in the United States;

(C) is marked and labeled as required by regulations for imported articles; and

(D) complies with the requirements of this section.

(2) Upon entry for consumption in the United States, fish or fish products satisfying the requirements of paragraph (1) shall be deemed to be and treated as domestic fish or fish products.

(b) INSPECTION OF IMPORTS.—The Secretary, in cooperation with the Secretary of the Treasury, shall enforce this section through random inspections and sampling of fish and fish products that are offered for importation or entered, or withdrawn from warehouse, for consumption in the United States, and through any other procedures the Secretary determines are necessary to ensure compliance with this Act.

(c) CORRECTIVE ACTIONS.—All fish and fish products that are refused entry pursuant to subsection (a) or that are entered, or withdrawn from warehouse, for consumption in the United States in violation of this section shall, pursuant to regulations, be destroyed unless—

(1) such fish and fish products are exported within a time fixed therefor by the Secretary; or

(2) the Secretary determines that any such fish or fish product can be brought into compliance with this Act by relabeling or other action.

If the Secretary determines that the fish or fish product can be brought into compliance, the destruction of such fish or fish product may be deferred pending filing of a written application by the owner or consignee and the execution by the applicant of a bond within a time specified by the Secretary. Upon such filing and execution of a bond, the Secretary may authorize the applicant to perform such relabeling or other actions specified by the Secretary. After such action is performed, if the Secretary determines that such fish or fish product has been brought into compliance with this Act, the Secretary shall permit its entry for consumption in the United States.

(d) COSTS.—Storage, cartage, labor, and other costs resulting from the denial of entry, or withdrawal from warehouse, of any fish or fish product shall be paid by the owner or consignee, and nonpayment of such costs shall constitute a lien against such fish or fish product and any other fish or fish product thereafter entered, or withdrawn from warehouse, by such owner or consignee, for consumption in the United States.

(e) FOREIGN PROGRAM.—(1) Upon request, the Secretary shall review the seafood safety and quality assurance program of each country desiring to export fish or fish products into the United States to determine if such program is at least equal to the program established under this Act.

(2) If the Secretary determines that a country desiring to export fish or fish products to the United States has a program at least equal to the program established under this Act and that such country will permit the enforcement measures determined to be necessary pursuant to paragraph (5), the Secretary shall issue a certificate to such country stating that the country maintains such a program.

(3) No fish or fish product shall be permitted entry for consumption in the United States from a country that does not have such a certificate that is valid and in effect.

(4) The Secretary shall periodically, not less than once every five years, review such certificates and shall revoke the certificate of any country that the Secretary determines is not maintaining a seafood inspection program at least equal to the program established under this Act.

(5) The Secretary shall enforce this subsection through the imposition of random inspections, sampling, and testing at such stages in the processing of fish or fish products, and such other actions as the Secretary determines are necessary to ensure compliance with this Act.

EXPORTS

SEC. 10. (a) STANDARDS.—Fish or fish products intended for export to a foreign country may be exempted from specific requirements of this Act if such exemption is necessary to avoid conflict with a law or custom of the importing nation. Fish or fish products so exempted shall be deemed not to be adulterated or misbranded under this Act if such fish or fish products—

(1) are in accord with the specifications of the foreign purchaser;

(2) are not in conflict with the laws of the country to which they are intended for export;

(3) are shipped in a package whose outside labeling states that the fish or fish products are intended for export; and

(4) are not sold, offered for sale, or otherwise disposed of in commerce within the United States;

except that any such fish or fish product shall be deemed to be adulterated if the Secretary determines such fish or fish product represents a significant hazard to the health of the eventual consumer.

(b) INSPECTION.—The Secretary shall inspect fish or fish products intended to be exported to foreign countries at such times and places and in such manner as the Secretary determines are necessary to ensure compliance with this Act.

(c) CERTIFICATES.—The Secretary shall, upon request, provide a certificate of export stating the condition of fish or fish products inspected under this section.

PROHIBITED ACTS AND PENALTIES

SEC. 11. (a) PROHIBITED ACTS.—No person shall—

(1) process any fish or fish product at any processing facility, except in compliance with this Act or any regulations promulgated thereunder;

(2) sell, transport, offer for sale or transportation, receive for transportation, or otherwise dispose of, in interstate commerce any fish or fish product that is adulterated or misbranded at the time of such sale, transportation, offer for sale or transportation, receipt for transportation, or disposal;

(3) commit, with respect to any fish or fish product, and while such fish or fish product is being transported in interstate commerce or held for sale after such transportation, any act that is intended to cause or has the effect of causing such fish or fish product to be adulterated or misbranded;

(4) sell, transport, offer for sale or transportation, receive for transportation, or otherwise dispose of, in interstate commerce any fish or fish product that is not processed in accordance with the requirements of this Act or any regulations promulgated thereunder;

(5) forge, counterfeit, or falsely represent any official mark or registration;

(6) without authorization from the Secretary, use any official mark or registration, or simulation thereof, or alter, detach, deface, or destroy any official mark or registration;

(7) refuse to permit entry or inspection to or on any processing facility, or otherwise interfere with any inspection or other person carrying out duties required under this Act; or

(8) create or maintain records that are false either by content or omission, or destroy records containing information required under this Act or any regulations promulgated under this Act.

(b) CIVIL PENALTIES.—(1) Any person who, after notice and opportunity for a hearing, violates subsection (a) shall be liable to the United States for a civil penalty in an amount not to exceed $10,000 for each violation. Each day of a continuing violation shall constitute a separate offense. In determining the amount of such penalty, the Secretary shall take into account the gravity of the violations and, with respect to the violator, the degree of culpability and history of prior violations (including violations resolved by written warnings), and such other matters as justice may require.

(2) The Secretary may compromise, modify, or remit, with or without conditions, any civil penalty that is subject to imposition or that has been imposed under this section.

(c) CRIMINAL PENALTIES.—(1) Any person who violates subsection (a) shall—

(A) be fined in an amount not to exceed $10,000, or imprisoned for not more than one year, or both; and

(B) if such violation involves intent to defraud, or any distribution of any fish or fish product that is adulterated, be fined in an amount not to exceed $20,000, or imprisoned for not more than three years, or both.

(d) NOTICE OF WARNING.—In the case of one or more minor violations of this Act or regulations promulgated under this Act, the Secretary may, whenever the Secretary believes that the public interest will be adequately served thereby, issue to the violator a suitable written notice of warning. In determining whether the public interest will be adequately served by a written notice of warning, the Secretary shall consider, among other factors—

(1) the compliance history of such person;

(2) the magnitude of the violation;

(3) whether compliance with this Act would likely be obtained as a result of such notice; and

(4) whether such violation is of a minor or technical nature.

(e) CARRIERS.—No common carrier or contract carrier shall be subject to penalties under this section for the receipt, carriage, holding, or delivery, in the usual course of business, as a carrier, of any adulterated or misbranded fish or fish product owned by another person, unless the carrier—

(1) during the time of such receipt, carriage, holding, or delivery, had knowledge or was in possession of facts that would cause a reasonable person to believe that the fish or fish product were adulterated or misbranded or were otherwise not eligible for transportation under this Act, or

(2) refuses to furnish on request of the Secretary the name and address of the person from whom the carrier received the adulterated or misbranded fish or fish product, and copies of all documents pertaining to the delivery of such fish or fish product.

HEARINGS AND SUBPOENAS

SEC. 12. (a) ADMINISTRATIVE HEARING.—The Secretary shall afford an opportunity for a written hearing to any person adversely affected by the action or inaction of the Secretary under this Act. As soon as practicable after such hearing the Secretary shall take appropriate action.

(b) SUBPOENAS.—(1) For the purposes of any hearing or investigation under this Act, the Secretary may issue subpoenas requiring the attendance and testimony of witnesses and the production of any documentation or other evidence that relates to any matter under investigation or in dispute before the Secretary and to administer oaths or affirmations.

(2) The Secretary shall pay witnesses subpoenaed under this subsection customary reasonable fees and mileage.

(3) In case of contempt or refusal to obey a subpoena served upon any person pursuant to this subsection, the district court of the United States for the district in which such person is found, resides, or transacts business, upon application by the Secretary and after notice to such person, shall have jurisdiction to issue an order requiring such person to appear and give testimony before the Secretary or to appear and produce documents before the Secretary or both, and any failure to obey such order of the court may be punished by such court as a contempt thereof.

EXEMPTIONS AND EXCLUSIONS

SEC. 13. (a) IN GENERAL.—This Act shall not apply to—

(1) the processing by any individual of fish and fish products of that individual's own raising or harvesting exclusively for use by that individual, or by that individual's household members, nonpaying guests, and employees; and

(2) vessels that harvest or commercially prepare fish or fish products unless they prepare fish or fish products other than by gutting, decapitating, gilling, icing, or brine chilling, as determined by the Secretary.

(b) INDUSTRIAL PRODUCTS.—This Act shall not apply to any processing facility solely processing fish products not intended for human consumption.

(c) STUDY.—(1) The Secretary shall, not later than eighteen months after the date of enactment of this Act, conduct and complete a study of—

(A) the role of vessels exempted under subsection (a)(2) in providing fish and fish products; and

(B) based on a scientific analysis conducted pursuant to the Hazard Analysis Critical Control Point method, the necessity of including any particular type or class of such vessels in the inspection program conducted pursuant to this Act.

The Secretary may from time to time update any such study.

(2) The Secretary shall submit to the Committee on Commerce, Science, and Transportation of the Senate and the Committee on Merchant Marine and Fisheries of the House of Representatives the results of the study required under paragraph (1) and the results of any update of such study.

(3) If as a result of the study conducted pursuant to paragraph (1) or any update of such study the Secretary recommends that any type or class of vessel exempted pursuant to subsection (a)(2) should be included in the seafood safety and quality assurance program established under this Act,

the Secretary shall, after public notice and an opportunity for comment, promulgate regulations to include any such type or class of vessel in such program.

CONSUMER EDUCATION AND INFORMATION

SEC. 14. (a) DESIGN AND IMPLEMENTATION OF PROGRAM.—The Secretary shall design and implement a national consumer education and information program on seafood.

(b) COLLECTION, ANALYSIS AND DISSEMINATION.—(1) Under the program referred to in subsection (a), the Secretary shall collect and analyze information on the health hazards associated with the human consumption of fish and fish products (including information on the number, causes, and geographic location of illnesses related to such consumption) and shall disseminate the results of such collection and analysis to consumers, persons involved in processing, and other interested persons.

(2) In the collection and analysis of information referred to in paragraph (1), the Secretary shall, among other things, assess such health hazards with respect to—

(A) fish and fish products that are commercially harvested and processed as compared with those harvested for recreational or subsistence purposes and prepared noncommercially;

(B) fish and fish products that are domestically harvested and processed as compared with imported fish and fish products that are harvested and processed outside the United States; and

(C) contamination originating from certain practices that occur both prior to and after sale of fish or fish products to consumers, especially in connection with the manner in which consumers handle and prepare the fish and fish products they purchase.

(3) In disseminating the results of the collection and analysis of information referred to in paragraph (1), the Secretary shall—

(A) inform consumers and persons involved in processing regarding the standards and good practice requirements prescribed under section 5 and promote public awareness, understanding, and acceptance of such standards and requirements;

(B) advise individuals involved in recreational and subsistence fisheries concerning the health hazards associated with the fish they may harvest and the precautions they should take to safeguard themselves and others from those hazards; and

(C) provide such other information or advice to consumers and other persons as the Secretary determines will promote the purposes of this Act.

(c) Designation of National and Regional Centers.—Under the program referred to in subsection (a), the

Secretary shall designate national and regional centers that will conduct, support, and foster research, investigation, experimentation, education, and training regarding seafood safety and quality assurance.

RESEARCH PRIORITIES

SEC. 15. (a) SHELLFISH INDICATOR RESEARCH PROGRAM.—(1) The Secretary shall establish and administer a five-year shellfish indicator research program to develop a system of classification of shellfish growing waters based upon the latest technological advancements in microbiology and epidemiological methods. In establishing such a program, the Secretary shall develop a program plan which shall provide for, but not be limited to, the following activities:

(A) Environmental assessment of commercial shellfish growing areas in the United States, including evaluation of the relationships between indicators of fecal contamination and human enteric pathogens.

(B) Evaluation of such relationships with respect to potential health hazards associated with human consumption.

(C) A comparison of the current microbiological methods used for evaluation of indicator bacteria and human enteric pathogens in shellfish and shellfish growing waters with new technological methods designed for this purpose.

(D) Design of epidemiological studies to relate microbiological data, sanitary survey data, and human shellfish consumption data to actual hazards to health associated with such consumption.

(E) Recommendations for revising the Federal standards established under section 5 and improving the capabilities of Federal and State agencies to effectively manage shellfish resources and ensure the safety of fish products containing shellfish.

(2) The research program established pursuant to this section shall evaluate representative estuaries in each of the major shellfish growing regions of the United States and shall result in development of recommendatons pertaining to shellfish management and regulatory considerations for each of the following shellfish growing regions:

(A) the New England region, consisting of the States north of New Jersey which border the Atlantic Ocean;

(B) the Mid-Atlantic region, consisting of Maryland, Virginia, Delaware, and New Jersey;

(C) the South Atlantic region, consisting of North Carolina, South Carolina, Georgia, and the Atlantic coast of Florida;

(D) the Gulf of Mexico region, consisting of Texas, Louisiana, Mississippi, Alabama, and the gulf coast of Florida; and

(E) the Pacific region, consisting of Hawaii, California, Oregon, Washington, and Alaska.

(3) The Secretary shall carry out the research program authorized by this section by providing assistance in the form of grants to eligible applicants. Not later than ninety days after the date of enactment of this Act, the Secretary shall publish in the Federal Register a call for research proposals to carry out the research program. Not later than ninety days after the date of such publication, the Secretary shall award a grant or grants to eligible applicants for carrying out the research program. As used in this paragraph, the term "eligible applicant" means—

(A) any public or private institution of higher education;

(B) any public or private organization with suitable research capabilities; or

(C) any consortium of two or more entities referred to in subparagraphs (A) and (B).

(4) The Secretary shall establish an advisory panel to assist in the development and implementation of the research program. Such advisory panel shall include one representative from each of the following agencies or organizations: the

Environmental Protection Agency, the Food and Drug Administration, and the Interstate Shellfish Sanitation Conference. In addition, the Secretary shall appoint an industry representative from each of the shellfish growing regions identified in paragraph (2) to serve on the advisory panel.

(5)(A) The Secretary shall review the research program authorized by this section not less than every two years and, on the basis of that review, make changes in the administration of the program that are appropriate to carry out more effectively the activities described in paragraph (1).

(B) The Secretary shall submit a biennial report to the Committee on Commerce, Science, and Transportation of the Senate and the Committee on Merchant Marine and Fisheries of the House of Representatives regarding the operation of the program. Each such report shall include, with respect to the period covered by the report—

(i) a description of the research assisted under the program and the results of such research; and

(ii) all changes to the program made under subparagraph (A) since the previous such report.

(C) At the completion of the research program, the final report submitted pursuant to subparagraph (B) shall include any recommendation for legislative action needed to improve the effectiveness of shellfish management and ensure the safety of shellfish and fish products containing shellfish.

(D). The final report shall be made available to appropriate Federal and State agencies, the shellfish industry, and the general public and shall be reviewed in a series of public hearings held in each of the five regions described in paragraph (2).

(b) OTHER RESEARCH.—The Secretary shall conduct and support research with respect to—

(1) testing the methodology for detecting and measuring biological and chemical contaminants in fish and fish product;

(2) techniques and procedures for inspecting fish and fish products;

(3) sanitation practices for the processing, transportation, and storage of fish and fish products; and

(4) any other matters that may further the purposes of this Act.

REGULATIONS

SEC. 16. The Secretary may promulgate such regulations as the Secretary determines are appropriate in carrying out this Act.

INTERAGENCY COOPERATION

SEC. 17. By agreement with the head of any Federal agency, the Secretary may utilize on a reimbursable basis or otherwise, the personnel, services, and facilities of any other department or agency of the United States in the performance of his duties under this Act.

AUTHORIZATION OF APPROPRIATIONS

Sec. 18. (a) In General.—There are authorized to be appropriated, to carry out this Act, not to exceed $35,000,000 for fiscal year 1991, $60,000,000 for fiscal year 1992, and $90,000,000 for fiscal year 1993.

(b) Research Program Authorization.—Of the funds authorized to be appropriated under subsection (a), there are authorized to be appropriated to the Secretary not to exceed $15,000,000 for each of fiscal years, 1991, 1992, and 1993, for carrying out the research program authorized by section 15.

○

STATEMENT OF HON. WILLIAM S. COHEN, U.S. SENATOR FROM MAINE

Senator Cohen. Thank you, Mr. Chairman.

I want to thank Senator Hollings and Senator Stevens for holding this important hearing. Seafood inspection is a critical issue these days. As we try to establish a sound and workable inspection program, hearings such as today's are crucial in order to expand and clarify the debate.

Last year, I joined Senator Mitchell and Senator Cochran in introducing S. 1245 which calls for a mandatory federal inspection program. The bill was drafted broadly and was intended to provide a framework for further debate on the matter of seafood inspection. In the past year, there has been tremendous debate in Congress on this issue and a workable seafood inspection program has come much more into focus. There has been extensive dialogue among the industry, consumer advocates and staff members of the Agricultural Committee and the Commerce Committee. They have all worked together to devise a workable seafood inspection program. While there have been disagreements along the way, a sense of cooperation and singleness of purpose has prevailed.

Through these lengthy discussions, a consensus has been reached on many of the substantive matters regarding seafood inspection. In fact, S. 1245 as amended is quite similar to S. 2228 introduced by Senator Hollings and Senator Stevens. Both call for a mandatory inspection program which is not supported by user fees. Both bills require the use of HACCP (pronounced hassip) methodology as means of assuring food safety, and both bills recognize that imported seafood products must be held to the same standards as domestic products.

Indeed, most of us agree on the substance of the inspection program. And, we certainly agree on the goal: to enact legislation this year that will, for the first time, estabish a mandatory seafood inspection program. Even regarding the matter of agency jurisdiction, I think there is more agreement than disagreement.

In its original form, S. 1245 did not provide for roles by the Department of Commerce or the Food and Drug Administration. In the course of the debate over the past year, however, it has become clear that these agencies have important roles to play in a seafood inspection program. While I still believe that USDA should be the lead agency for the program, the expertise and experience of the Committee Department and the FDA should also be drawn upon to produce the best possible inspection program. Accordingly, S. 1245 as amended now provides for significant cooperating roles for both the Commerce Department and the FDA.

A year ago, we began the process of devising a mandatory seafood inspection program. After months of debate, there is a general consensus as to how the program should operate. I am hopeful that these areas of agreement will be built upon to produce a good piece of legislation and that we won't become bogged down on issues related solely to agency jurisdiction.

Again, I commend Senator Hollings and Senator Stevens for initiating this hearing. I am sure that it will add constructively to the debate on this matter and remain hopeful that we will be able to enact legislation this year.

The **Chairman**. The jurisdiction will not hold it up. We can resolve it, I am confident.

We hesitated at that particular time, Senator, in all candor, because we wanted to look at the existing programs. We were wondering what was happening at NOAA and FDA. We found out that the program is somewhat thorough with respect to our imports, but not domestically and not covering, frankly, all of interstate. But there is great potential for cooperation with the states.

Senator Mitchell.

STATEMENT OF HON. GEORGE J. MITCHELL, U.S. SENATOR FROM MAINE

Senator **Mitchell**. Mr. Chairman, thank you very much for this hearing and for permitting me to testify. And I also want to thank you and Senator Stevens for your traditional leadership on issues of importance to the fishing industry, and for your assistance in passing the lobster bill during the first session of the 101st Congress. That lobster bill was important to all of New England, and yours and Senator Stevens' support of the bill particularly represented a commitment by East and West coast fishing industries to work together. That commitment has been recognized and appreciated throughout New England.

It is my hope that the same bipartisan, bicoastal spirit will prevail on the fish inspection legislation.

Mr. Chairman, almost a year ago I introduced S. 1245, a bill to establish a national fish inspection program. The bill has since been cosponsored by 28 senators, including Senator Cohen, and six members of the commerce committee, including yourself, Mr. Chairman, and Senator Kerry.

On March 1 of this year, Mr. Chairman, you and Senator Stevens introduced S. 2228, which I and Senator Kerry also joined as cosponsors. Earlier this week the Senate Agriculture Committee marked up and approved S. 1245. The Agriculture Committee bill reflects many concepts and features derived from both your bill and another bill, S. 1983, introduced by Senator Leahy.

While I am pleased with the overall result of the Agriculture Committee's action, I would like to express my disappointment with one omission in the bill as reported by the Agriculture Committee. On a close 10 to 9 vote, that committee deleted a whistleblower protection provision from the committee substitute. This provision is an essential safeguard for public health interests in any program that provides less than continuous inspection.

The provision deleted by the Agriculture Committee reflected recent existing precedents under federal law, and in fact was modelled after the 1982 Surface Transportation Assistance Act crafted by this Senate Commerce Committee. I hope that we are able to restore a strong whistleblower protection provision in the bill. I would not support enactment of legislation that failed to include an adequate provision in that regard.

Overall, I think the bill reported out with that one omission is a solid, sensible bill. There are issues which still need to be worked on, but there is a consensus on many aspects of the legislation.

Senator Cohen touched on the question of agency role and jurisdiction. That is important, and I would like to address that, Mr. Chairman. I ask unanimous consent that the full text of my statement be placed in the record. It is a lengthy statement and I am just going to refer to portions of it.

The CHAIRMAN. It will be included.

Senator MITCHELL. Mr. Chairman, S. 1245 establishes the Department of Agriculture as the lead agency for federal fish inspection. But it also provides important roles for the Food and Drug Administration and the National Oceanic and Atmospheric Administration. The lead agency with responsibility for such a program should be the Department of Agriculture on both grounds of equity and effectiveness.

The Food Marketing Institute has determined that consumer confidence is highest in the Department of Agriculture. USDA has responsibility for the inspection of meat and poultry products, the fishing industry's primary competitors. Meat and poultry inspections are funded by the Federal Government. The fishing industry should not be subjected to inspection by a different agency with a different level of consumer confidence, nor be required to pay for an inspection system while its competitors are inspected under a federally-funded system directed by USDA, which has a high level of consumer confidence.

That would be unfair and inequitable to the fishing industry. The choice of USDA also reflects a recognition that the fishing industry is part of a global market place. And the Department of Agriculture is best positioned to support the industry to achieve global competitiveness.

Jurisdictional issues should not be allowed, however, to prevent enactment of legislation that serves the public interest. As reported by the Agriculture Committee, S. 1245 envisions interagency cooperation and draws on existing strengths within each agency. At a time of scarce budget resources, Congress should insist on such interagency cooperation, as well as streamlining and strengthening of individual agency missions.

The Senate Committee on Labor and Human Resources recently reported an FDA revitalization bill, S. 845, which currently is pending on the Senate calendar. In its report, the committee specifically directs FDA to undertake a management study to determine, in part, and I now quote the committee report, "which of the agency's responsibilities can more efficiently be performed by the private sector, other federal or state agencies, or because of changes in technology, no longer need to be regulated by FDA."

According to testimony by the Coalition for FDA Resources, the agency's own supporters, before a House appropriations subcommittee, FDA's response to its current staff shortage, and I quote, "has been to slight some duties in favor of others, to develop sampling and compliance targeting techniques to compensate for decreased monitoring capabilities, and in the end, to rely on honor systems."

That statement reaches the heart of the issue. FDA's current program is reactive rather than proactive, and is inadequate and incommensurate to the needs of both American consumers and the American fishing industry.

The President of the National Academy of Sciences Institute for Medicine has been quoted as saying that the FDA, and I quote, "is a demoralized group, asked to do too much with too few resources."

Neither Congress nor the Administration can have it both ways. If FDA needs revitalization, then it cannot fulfill current needs by undertaking a major new program for federal fish inspection. Nor can it shortchange consumers and fishermen by seeking to hold tightly to responsibilities that it cannot now adequately fulfill.

The role and mission of the National Oceanic and Atmospheric Administration must be considered in federal fish inspection legislation. There is an urgent need for greater scientific research, greater fisheries conservation and management efforts, and greater fisheries enforcement by NOAA.

In an era of scarce resources, we must insist in interagency cooperation for a comprehensive fish inspection program, and S. 1245 does just that.

I welcome the Commerce Committee's assistance in continuing progress on this legislation.

[The statement follows:]

Testimony of
Senator George Mitchell
Senate Majority Leader

before the
Committee on Commerce, Science & Transportation
and National Ocean Policy Study

May 24, 1990

I want to begin my testimony be saying thank you again to Senator Hollings and Senator Stevens, for their traditional leadership on issues of importance to the fishing industry, and for their assistance in passing my lobster bill during the First Session of the 101st Congress.

The lobster bill was important to all of New England. Senator Stevens' support of the bill particularly represented a commitment by the East and West Coast fishing industries to stand or fall together in their interests. That commitment has been recognized and appreciated throughout New England.
It is my intention that the same bipartisan, bicoastal spirit should prevail relative to fish inspection legislation.

Whether it is in New England or the Pacific Northwest, the Gulf of Mexico or elsewhere, whatever affects the quality of seafood, and whatever affects the confidence of consumers in the seafood marketplace, utlimately affects the livelihood of all fishermen.

Almost one year ago, I introduced S.1245, a bill to establish a national fish inspection program. I was encouraged to do so by leaders of Maine's fishing industry---including the Associated Fisheries of Maine, the Maine Sardine Council and the Maine Fishermen's Cooperative Association. The bill has since been co-sponsored by 28 Senators, including 6 members of the Commerce Committee.

The staffs of both the Commerce Committee and that of the Senate Agriculture Committee have worked with my own staff in efforts to define and refine specific concepts for such legislation. During a three-week period beginning January 25 and ending February 9, 1990, the combined staffs participated in a series of informal discussions on fish inspection with representatives of various Federal agencies and both industry and consumer organizations.

On March 1, 1990, Senator Hollings and Senator Stevens introduced S.2228, an additional fish inspection bill. Along with Senator Kerry, I joined as an original co-sponsor of that bill. Senator Hollings and Kerry also co-sponsored S.1245.

In a Floor Statement included in the Congressional Record on March 7th, I expressed my view that S.2228, along with a third bill, S.1983, introduced by Senator Leahy, Chairman of the Agriculture Committee, represented "a logical progression" from the original S.1245 in the legislative process. Senator Hollings and my co-sponsorship of S.1245 and S.2228 respectively also was an expression of our commitment to work together to achieve sound, sensible legislation.

Earlier this week, the Senate Agriculture Committee marked-up and approved S.1245. The Agriculture Committee bill substitute reflects many concepts and features derived from both S.1983 and S.2228.

I want to state for the record my disappointment with one omission from S.1245, as reported by the Agriculture Committee. On a close 10-9 vote, the Committee deleted a "whistleblower protection" provision from the Committee substitute. This provision is an essential safeguard for public health interests in a program that provides less-than-continuous inspection.

The whistleblower provision deleted by the Senate Agriculture Committee reflected recent, existing precedents under Federal law. It was modeled particularly after the 1982 Surface Transportation Assistance Act---which was crafted by the Senate Commerce Committee. Today, I want to make clear my intentions on this particular issue. I intend to work to restore a strong whistleblower protection provision in the legislation. I will not support enactment of legislation that fails to include an adequate provision in this regard.

Overall, I want to state, however, that S.1245 is a solid, sensible bill. There are issues which still need to be worked on, but there is consensus on most aspects of the legislation. I am especially grateful for the work devoted to the legislation by the National Fisheries Institute and Public Voice for Food & Health Policy. These organizations are not testifying in today's hearing, but they already have provided critical testimony before other Senate and House committees.

S.1245 contains many important features: it reflects the basic principles that the Federal Government should fund a mandatory fish inspection program directly as a public health program; that inspections should be based on reasonable risk assessments under the Hazard Analysis Critical Control Point method; and that imported products must be subject to the same standards as our domestic industry.

S.1245, as approved by the Senate Agriculture Committee, also includes many provisions refined in Senator Hollings' and Senator Stevens' S.2228, such as providing a role for the Interstate Shellfish Sanitation Conference; creating a Shellfish Indicator Research Program; and placing an emphasis on cooperation with State Governments and minimizing disruption to the fishing industry through a prioritized, gradually phased-in approach.

The issue of agency roles and jurisdiction also is important.

S.1245 establishes the U.S. Department of Agriculture (USDA) as the lead agency for Federal fish inspections. However, it also envisions important roles for the Food & Drug Administration (FDA) and the National Oceanic and Atmospheric Administration (NOAA).

It is no secret that my preference for agency responsibility for such a program is the Department of Agriculture. I view this as an issue of equity and effectiveness.

The Food Marketing Institute has determined that consumer confidence is highest in the Department of Agriculture. USDA has responsibility for the inspection of meat and poultry products, the fishing industry's primary competitors. Meat and poultry inspections are funded by the Federal Government at a cost of $400 million annually. The fishing industry should not be subjected to a different agency, nor be required to pay for an inspection system, while its competitors are inspected under a Federally-funded system.

The choice of USDA also reflects a recognition that the U.S. fishing indusry is part of a global marketplace, and USDA is best-positioned to support the industry to achieve global competitiveness. USDA already has an overseas network of trade officials and inspectors. The Federal Government's negotiating posture in current GATT negotiations also is to regard fisheries products as agricultural commodities. Fish inspection standards will become an increasingly important aspect of international trade.

USDA is a choice for the future. Congress must not rely soley on bureaucratic arrangements of the past in legislating a comprehensive Federal fish inspection program.

I also have stated that jurisdictional issues should not be allowed to prevent enactment of legislation that truly serves the public interest. As reported by the Senate Agriculture Committee, S.1245 envisions interagency cooperation and draws on existing strengths within each agency.

In an era of scarce budget resources, Congress should insist on interagency cooperation, as well as a streamlining and strengthening individual agency missions.

Last week, the Administration commented on S.2393, the "Safe Food Transportation Act of 1990," which was approved by the Commerce Committee on April 3, 1990. It is not my purpose to comment on the merits of that bill today; however, the letter of comment which was jointly signed by the Secretary of Health & Human Services and the Secretary of Agriculture, along with the EPA Administrator and Secretary of Transportation should be noted: "The Administration will support legislation which 1) allows for adequate flexibility in developing and executing a regulatory program," and 2) recognizes existing agency expertise and experience."

The Administration letter on S.2393 indicated the USDA, FDA and EPA "need to play the primary role for determining standards for food safety." Moreover, "the relevant agencies will work together to make the full use of their expertise to develop and execute an effective program, regardless of the final division of responsibility."

Looking to USDA and FDA as the nation's primary food safety agencies, I believe the same flexible approach should be adopted by the Administration in the area of fish inspection. The need to streamline and strengthen agency roles and missions is especially relevant to FDA and NOAA.

The Senate Committee on Labor & Human Resources recently reported an FDA Revitalization bill, S.845, which currently is pending on the Senate Calendar. In its report, the Committee specifically directs FDA to undertake a management study to determine in part "which of the agency's responsibilities can more efficiently be performed by the private sector, other Federal or State agencies, [emphasis added] or because of changes in technology, no longer need to be regulated by FDA."

FDA's budget for all food safety activities currently is approximately $145 million. The estimated cost of a Federal fish inspection program is up to $100 million---approximately 70 percent of FDA's current budget for food activities. According to a recent General Accounting Office (GAO) report, the FDA has estimated that it needs 2,000 additional positions ---more than a 25% increase in staff---just to administer current programs.

According to the GAO Report, FDA officials said that these additional 2,000 positions still would not allow FDA to expand its seafood inspections.

According to testimony by the Coalition for FDA Resources, the agency's own supporters, before a House Appropriations Subcommittee, FDA's response to its current staff shortage "has been to slight some duties in favor of others, to develop sampling and compliance monitoring techniques to compensate for decreased monitoring capabilities, and in the end to rely on 'honor systems.'"

That statement probably strikes to the heart of the issue. FDA's current program is reactive, rather than proactive; and is inadequate and incommensurate to the needs of both American consumers and the fishing industry.

The president of the National Academy of Sciences' Institute for Medicine is quoted as stating that FDA "is a demoralized group, being asked to do too much with too few resources."

Neither Congress nor the Administration can have it both ways. If FDA urgently needs revitalization, then it cannot fulfill current needs by undertaking a major new program for Federakl fish inspection; nor can it short-change consumers and fishermen by seeking to hold tightly on to responsibilities that it cannot adequately fulfill.

From the same perspective, the role and missions of the National Oceanic & Atmospheric Administration must be balanced in considering Federal fish inspection legislation. There is a very urgent need for greater scientific research, greater fisheries conservation and management efforts, and greater fisheries enforcement by NOAA.

FDA's revitalization and NOAA's expanding role in other areas must not be jeopardized. In an era of scarce resources, Congress should insist on interagency cooperation for a comprehensive fish inspection program. S.1245 does exactly that with USDA, FDA and NOAA, seeking to build on the strengths of each agency. I welcome the Commerce Committee's assistance in continuing progress on the legislation.

The CHAIRMAN. Very good. I will just make a couple of comments and yield to my colleagues in order of their arrival—Gore, Breaux and then Cohen. Is that all right?

Senator Mitchell, right to the point. You know, under the Agricultural Marketing Act of 1946 they call on NOAA for the voluntary seafood inspection that is going on right now. Now, they only cover anywhere from 9 to 12 percent of the seafood consumed. They have about 300 people involved in seafood safety programs and a very limited budget of around $20 million which is provided in part, by industry fees. The FDA has a smilar size program. They say they now inspect about 25 percent, let us say, of seafood processing plants, with 300 personnel and another $20 million annually.

On the issue of consumer confidence—the public has confidence in the Department of Agriculture because that is all they really know about. And even there we have a problem, according to a film I saw on agricultural meat inspection just about a month ago. But we can chat about that later. In any event, we have got 128,000 fishing vessels, and seafood safety is a totally differnt thing to control than meat and poultry inspection. Seafood requires a different kind of approach.

The question really evolves as to whether or not the Food and Drug Administration, the National Oceanic and Atmospheric Administration, need to be beefed up with the National Marine Fisheries Service, the NOAA labs, and everything else all there. The alternative is whether the expertise is to be transferred to USDA. If we agree to the approach in your bill, they would have to transfer two to three offices which are already in existence at NOAA and FDA over into the Department of Agriculture. From your comments, which I agree with thoroughly, the problem really is that they have not had a very extensive or financially supported program at NOAA and FDA.

But let me yield to Senator Gore, because we want to move to the Secretary. Secretary Sullivan has to leave at 10:00 a.m., and you are behind schedule, too. Go ahead.

Senator GORE. Well, in light of that, Mr. Chairman, I will forego any questions.

The CHAIRMAN. Very good. Senator Breaux.

Senator BREAUX. I was just wondering if I could ask the witness if he knows what time we are going to get out this evening?

I would just like to thank him. He has done a lot of good work on this. I appreciate the work that the majority leader has done.

The CHAIRMAN. Senator Cohen.

Senator COHEN. No questions.

The CHAIRMAN. Thank you very, very much.

Senator MITCHELL. Mr. Chairman, thank you very much. I appreciate the courtesy of my colleagues.

The CHAIRMAN. Yes, sir—good. Secretary Sullivan. Mr. Secretary, we welcome you to the Committee. We are glad to see that your interest is varied—broader than cigarettes—and that it includes seafood.

Secretary SULLIVAN. Thank you very much, Mr. Chairman.

The CHAIRMAN. I would smoke fish.

Do you oppose that, too?

Secretary SULLIVAN. As long as you are 18 or over, I think you could.

My colleague from the FDA says as long as the FDA inspects it, it is all right.

The CHAIRMAN. We also welcome Dr. John Knauss, the Under Secretary of Commerce and Administrator of NOAA, James Benson, the Acting Commissioner of the Food and Drug Administration. Thank you very much, Mr. Secretary, and you may proceed.

STATEMENT OF HON. LOUIS SULLIVAN, SECRETARY, DEPARTMENT OF HEALTH AND HUMAN SERVICES

Secretary SULLIVAN. Thank you very much, Mr. Chairman.

It is always a difficult act to follow the majority leader concerning an issue like this, but perhaps it would simplify it if we could redefine fish as a meat, and then there would not be a jurisdictional issue. But obviously, Mother Nature will not cooperate with us in that, so we are confronted with a very different kind of issue when it comes to seafood inspection as compared to the inspection processes that exist in the Department of Agriculture for meet and poultry.

As you have already indicated, Mr. James Benson, our Acting Commissioner for the Food and Drug Administration is with me, along with Dr. John Knauss from the Commerce Department's NOAA Division.

Now, today's hearing does represent the culmination of a year of strong congressional interest and inquiry into virtually every aspect of the seafood program. Committees in both chambers have raised questions on how the Federal seafood program should be structured, which agency or agencies should have this responsibility, and the level of funding required.

I commend this collective analysis as well as your own personal interest, Mr. Chairman, in this subject. As you know, the Administration has also been studying seafood inspection over the past several months, and as the Nation's chief health officer, I assure you no one is more concerned about the safety of our seafood.

Our data suggests that although consuming raw shellfish carries a somewhat greater risk, seafood is on average safer than animal protein products such as chicken, and in short there is no public health crisis in seafood safety which might justify an upheaval in the existing programs.

This is not to say that we are satisfied with the current situation, because Congress and the Administration realize that the public may be uncertain as to the safety of seafood. The consumer needs and deserves the reassurance about safety that will be provided by an enhanced seafood inspection program. The Administration has concluded that the best way to improve the Federal seafood safety program is to build upon existing programs in the Department of Commerce and the Food and Drug Administration and to finance those enhanced services which impart substantial private benefit to the industry through user fees.

A letter outlining the Administration's views on this matter has been transmitted to the Congress by White House Chief of Staff

John Sununu, and I ask that that letter be made part of the record of today's hearing.

The **Chairman**. It will be included.[1]

Secretary **Sullivan**. Thank you. Mr. Chairman, your bill—S. 2228—contains many positive features that would strengthen seafood programs. Your bill emphasizes the critical points of harvesting, processing and transport of seafood where health risks are most likely. The inspection of processing vessels is also included, and a strong role is preserved for State inspection programs. We in the Administration want to work with you and the members of your Committee to improve the existing seafood program both at the Department of Commerce and the Food and Drug Administration.

The Administration believes that the Food and Drug Administration should continue in its current role in the leader of seafood safety given its public health mission, its experience and its expertise.

The Department of Commerce's responsibilities in seafood inspection and grading and in support of State inspection programs should be continued and enhanced, and be closely integrated with those of the FDA. The FDA operates a mandatory seafood safety program and has done so for many years. The law requires FDA to ensure that seafood is safe and wholesome and that it is not misbranded or deceptively packaged, just as it does for all other foods except meat and poultry, which is regulated by USDA.

The FDA inspects processors, suppliers, packers, warehouses and labelers of fish and fish products. FDA also examines and samples imported seafood products, and as you know, the Department of Commerce's National Marine Fisheries Service operates a mandatory seafood inspection program which allows members of the industry to display a seal showing that they have passed Federal inspection.

Under a current working agreement, the National Seafood Marine Fisheries Service program conducts seafood inspections looking for violations of the Food, Drug and Cosmetic Act. This program and the FDA also coordinate their research activities under a similar agreement. Both of these programs require a thorough understanding of marine biology and related marine disciplines. Our two agencies have acquired this expertise over the course of many years, and both have substantial interaction with the States, with other Federal agencies, and with foreign countries.

Under a new initiative in the Administration's fiscal year 1991 budget, these two agencies are working together to establish and implement a voluntary seafood program that is based on the model seafood surveillance program established by this Committee through your leadership, Mr. Chairman. This new program employs the Hazard Analysis and Critical Control Point principles.

The National Marine Fisheries Service will conduct the routine inspections of seafood plants and FDA will perform verification inspections to ensure proper functioning of the program. This demonstrates the commitment of the Administration to improving and strengthening our seafood programs.

---

[1] The letter was not reproducible.

Under new legislation, the two agencies are prepared to create jointly a comprehensive seafood program that includes the following: (1) setting standards for water quality, allowable containment levels and quality of seafood products; (2) inspecting and registering vessels and processing facilities; (3) strengthening inspections for imported seafood; (4) expanding consumer education programs about proper purchasing, handling and preparation of seafood; and (5) toughening record-keeping requirements, documentation and access for monitoring purposes.

As you know, Mr. Chairman, many of these elements are also part of your effort on model programs.

I would be remiss if I did not mention the strong role that our States share in seafood safety. State regulatory agencies rely on research and assistance from both the Food and Drug Administration and the National Marine Fisheries Service. The Interstate Shellfish Sanitation Conference exemplifies an effective Federal-State industry partnership to improve shellfish sanitation. This is but one part of the cooperative foundation to improve seafood safety. The cooperative service agreements, which are an essential part of the National Marine Fisheries Service and the FDA comprehensive seafood proposal, will allow the agencies to strengthen their relationships with the States.

The two agencies run a number of inspection and research laboratories which complement each other. For example, the Department of Commerce operates seafood utilization research laboratories in Charleston, Seattle and Gloucester, Massachusetts, and the National Seafood Inspection Laboratory in Pascagoula, Mississippi. FDA operates a seafood products research center in Bothell, Washington. The Fishery Research Branch Laboratory in Dauphin Island, Alabama, a shellfish sanitation, training and State assistance facility in North Kingston, Rhode Island, and 19 field laboratories with seafood expertise.

Another example of interagency cooperation results from an interest of yours, Mr. Chairman, and of Senator Stevens, in the health effects of Omega-3 fatty acids derived from fish. Through your leadership, financing has been provided for a Department of Commerce project which supplies the high quality fish oil test materials needed by my own Department's researchers to investigate the therapeutic effect of including these oils in one's diet.

Although there are potentially many risks to which seafood may be exposed, the actual range of reported health problems associated with seafood is relatively narrow. The clearest health risk involves the consumption of raw molluscan shellfish, and that stems largely from human pollution of coastal waters.

The best strategy for protecting the public from this risk is to monitor the water quality of growing areas. The National Shellfish Sanitation Program which is administered by the FDA is a cooperative Federal, State and industry endeavor to ensure that shellfish harvesting occurs only from waters certified to be safe. A critical component of water quality monitoring is the ability to rapidly detect contaminants, primarily viruses and bacteria which can concentrate in shellfish. This is an area of on-going successful research by both the FDA and the Marine Fisheries Service. For example, a recent advance allows us to detect the Norwalk Virus, which is responsible for most illnesses caused by eating raw molluscan shellfish.

In closing, Mr. Chairman, my message to you today is, we have a good seafood inspection program now. It works, and the right Federal agencies—those with seafood expertise—these agencies are running it. However, we can and we should improve our operations to bolster public confidence in seafood safety. Congress and the public want and expect this of us. We think that, using your bill as a starting point, we can work together and arrive at legislation that will help us make the needed improvements. We look forward to working with you and this Committee towards that end.

That concludes my prepared remarks, Mr. Chairman, and as you have noted I am scheduled to testify at another Committee, but I would be pleased to receive questions if you would like.

The **Chairman**. Yes. Secretary Sullivan, is the Committee to understand that this is the Administration's position? In other words, Secretary Yeutter of Agriculture is coordinated with you on your testimony here this morning?

Secretary **Sullivan**. Yes. We have had meetings involving Secretary Mosbacher, Secretary Yeutter and myself and OMB Director Darman, and this is the Administration's position coming out of those meetings.

The **Chairman**. Very good. With the press of time, let me yield to our colleagues.

Senator Breaux.

Senator **Breaux**. Thank you. I will just ask, following up on the Chairman's question, who should be the lead agency—has the Administration made an official recommendation and what is it?

Secretary **Sullivan**. Yes. The Administration's recommendation is that the Food and Drug Administration should be the lead agency in cooperation with the National Marine Fisheries Service.

Senator **Breaux**. What role would Agriculture have?

Secretary **Sullivan**. Agriculture's role presently is minimal. We have within our department, the Department of Health and Human Services, not only the FDA with its inspection capability, but also the Centers for Disease Control and the National Institutes of Health; we have the capability of detecting and analyzing many viruses and bacteria because——

Senator **Breaux**. I understand the capabilities of FDA. But my concern is, is Agriculture under the Administration's recommendation essentially excluded?

Secretary **Sullivan**. Yes.

Mr. **Benson**. May I?

Senator **Breaux**. That is a simple answer. I accept that. Let me ask another question—I think that the concern I have is, what are we inspecting for? History tells us that fish problems from a safety standpoint—a health standpoint—are minimal. Approximately 5 percent or less of food-related problems are from fish, less than 3 percent from fin fish, less than 3 percent from shellfish. It is not a big health problem.

There is another problem out there, though, it is a quality problem. It is a quality problem when someone sells stuffed shrimp, and they stuff 99 percent with bread and 1 percent with shrimp. That is a quality problem. And is the FDA—do you have an ability to get into that aspect of grading? Does the FDA propose to grade fish as USDA grades meat?

Mr. BENSON. The present authority for FDA includes dealing with quality. I think the industry's concerns are that we have placed adequate emphasis on safety but not adequate emphasis on quality issues.

Senator BREAUX. I agree with that.

Mr. BENSON. And I do too. Under the Administration's plan, we would in conjunction actually with NOAA taking the leadership role, pay much more attention to the quality end of it and, in fact, would have a mark that would be placed on seafood products that met the combined requirements or recommendations of the two agencies.

Senator BREAUX. So you would grade for quality. And the program under your proposal would be paid for by whom?

Mr. BENSON. May I?

Secretary SULLIVAN. Yes.

Mr. BENSON. The program that is envisioned by the Administration would be a combination of authorized funds as well as user fees.

Senator BREAUX. What would be the percentage breakdown?

Mr. BENSON. The present level of spending for FDA is about $25 million. The President's budget requests an additional $9 million for 1991 which would take it up to 34. I am not—Dr. Knauss ought to answer—I would defer to him on NOAA's present budget.

Senator BREAUX. Would it be a 50-50 split?

Mr. BENSON. I think that question will not be known until we get into the program, because there is no requirement for the industry to join. But I would say ultimately it could be on the order of 50-50. I think that is probably a good goal.

Senator BREAUX. And what is the rationale, where the poultry and meat industries pay zero for inspection programs, for the fishing industry to pay half of the cost?

Mr. BENSON. I think that is a very good question. The best answer I can give you on that is, we did some calculations, and it looks to us as if the existing regulatory program in USDA for meat and poultry per consumer dollar spent costs about 16 times as much as what FDA spends.

So it is a question of, I think, what the Congress wants to spend on these kinds of programs. It really—I think it is a function of what Congress tells us to do. If more money should be spent on seafood, then, that money should be authorized, and we will spend it. I can assure you.

Senator BREAUX. Thank you, Mr. Chairman.

The CHAIRMAN. Senator Cohen.

Senator COHEN. Mr. Chairman, if I could follow up on that particular issue. On the one hand, you have got a situation where seafood on the whole is safer than poultry, according to the Secretary's testimony. But you would have meat and poultry inspection funded by the taxpayer, but fish inspection, funded at least in part, by the fishing community.

And I am wondering, if we use the Darman duck test, which I know the Chairman is familiar with that. But if you call it a user fee, it is not a tax then. But I have a real question on the issue of uniformity and equity as to why the fishermen should be compelled to pay for inspection, even though it is a voluntary program as you have suggested. But meat and poultry are funded by the taxpayer. And I do not understand the disparity.

The notion that somehow that they are spending 16 times more money on their inspection does not really pertain to quality. Because, according to the GAO, there are some real problems within FDA itself. As a matter of fact, GAO says, FDA needs 2,000 more people just to administer the current programs. So I do not know that you can say because it takes 16 times more to fund the meat and poultry, therefore, you are more efficient.

Mr. BENSON. I think it is a question of cost-effectiveness and what you want out of what you spend. I think from a safety standpoint both programs, both USDA's program and FDA's program are exemplary.

I think from a quality standpoint, it is obvious that when you are spending 16 times as much, you are going to get more value back for that. I hope you get more value back from that. I think it is a question of what is an appropriate breakdown on the cost-effectiveness scale.

As far as the GAO recommendations are concerned, I believe that FDA operates an extremely cost-effective program across the board. I am proud of the things we do. There is no question in my mind that, you know, additional resources would enhance a lot of different programs.

Senator COHEN. Mr. Benson, let me ask you quickly. If you were given this jurisdiction, would you hire 2,000 more people, that GAO says you need, just to administer current programs without even getting into fish inspection on a wide-scale basis?

Mr. BENSON. That is a hard question to answer simply. Certainly, if we got the 2,000 the GAO is talking about, they would not all go to the fish inspections. They would not. I think right now we are getting an additional $9 million assuming the budget goes through. If the President's request is approved here, then, we would have the additional $9 million. That to me will strengthen the program enormously in conjunction with what NOAA is doing.

Senator COHEN. You have a $145 million budget now. And the cost of inspection, according to Senator Mitchell's testimony is that, it would cost about $100 million to have this inspection program for fish.

Do you think $9 million is going to make up the difference for you to assume greater jurisdiction?

Mr. BENSON. I am sorry, I do not know where the $145 million comes from.

Senator COHEN. FDA budget.

Mr. BENSON. Not for seafood, sir.

Senator COHEN. For inspection programs.

Mr. BENSON. Oh, across the board inspection programs.

Senator COHEN. Right.

Mr. BENSON. I am sorry, I misunderstood you.

Senator COHEN. Right, so now you are talking about a $9 million increase to the budget for inspection, and that is going to adequately fund the program?

Mr. BENSON. I think that it will continue to assure safety. I think that it is going to take the voluntary portion of that program based on user fees to get the quality up to where the industry would like to see it.

Senator COHEN. One final question, Mr. Chairman. If user fees were to be considered or imposed, and you hired additional people, what guarantees do we have that the fishing community is not paying a tax called a user fee in order to hire more inspectors that will be applied to other programs?

Secretary SULLIVAN. Well, let me comment on this. Senator Cohen, first of all, we have in our 1991 budget an overall request for additional FTEs for the Department, including I believe some 550 for the Food and Drug Administration. This is for a variety of programs within the FDA.

We are facing, as are all federal agencies, the challenge of meeting our responsibilities in our current economic environment. In view of the budget deficit, I think—which all of us are concerned about—the strategy for trying to meet those responsibilities while also being fiscally responsible in terms of our deficit has led us to the position of user fees.

In the final analysis, the Congress is going to decide on whether this would be financed by user fees or by direct appropriations. We have proposed this as a strategy, trying to be responsive to our programmatic responsibilities as well as to the fiscal budget. But, really, I think the Congress in its wisdom will determine how this would be financed, whether it is in Agriculture or in the FDA.

The CHAIRMAN. Good. As we all know, Mr. Benson and Dr. Knauss both will stay with us. Secretary Sullivan has to leave at 10 o'clock for another hearing.

Senator Stevens.

Senator STEVENS. Mr. Secretary, do you envision that the inspection program needed for seafood is different than the one needed for meat and poultry?

Secretary SULLIVAN. Very definitely. The meat and poultry program is one of largely visual inspection of a relatively narrow range of protein elements. In dealing with seafood, you have a tremendous variety of different organisms here, and, in contrast to domesticated animals for meat and poultry, largely you are dealing with species that are caught in the wild with tremendous variation.

That is why we have qualitative differences, and that is also why we emphasize our linkage within my department of the FDA to the NIH and CDC. The expertise to carry out the kinds of inspection for contaminants, for viruses or bacteria or toxins in seafood demands that kind of expertise. It exists now in my agency. That is not in the USDA. If this program were in the USDA, they would have to develop that expertise which we already have.

Senator STEVENS. I am inclined to agree with that.

I recognize the fact that you have to leave, and I will just make a statement to you. Every time seafood starts to have a higher proportion of the market, we find these charges that come from consumer groups, in quotes as far as I am concerned, about seafood.

I have lived through now the swordfish problem where we banned the swordfish industry for two years because of complaints.

We had a period of time when all halibut that was caught in the North Pacific over 150 pounds was destroyed because someone said mercury was a terrible thing.

We then went through a whole period of time when we had a salmonella scare, and it took me two to three days, I think, here in this committee to convince people we were talking about chicken and not salmon.

I have to tell you, I think that this whole thing needs a little bit of examination as to the real reason why we need any increased inspection beyond what we have now. My state has a zero tolerance. You find one fish in a load that is bad, we destroy the whole load. Agriculture does not destroy the whole area's production of meat if they find one bad block of meat.

We are processing millions of fish per day in plants that are 2,000 miles from my home in Anchorage, which is closer to Tokyo than it is to Washington, DC. If we start running a program out there of individual fish inspection, it is going to cost the consumer so much it will take the fish once again out of the spectrum as far as increased market share of the total demand for meat and fish products in this country.

I really hope you all will think twice about even what you are recommending. I think it is going too far.

The CHAIRMAN. Senator Robb.

Senator ROBB. Mr. Chairman, because I had a conflict and missed the earlier testimony, because there is a vote on, and because the Secretary has to be at another meeting, I know, in just a couple of minutes, I will rely on the record.

The CHAIRMAN. Very good.

Dr. Knauss, you and Mr. Benson stay with us.

Secretary Sullivan, thank you very, very much.

Secretary SULLIVAN. Thank you, Mr. Chairman.

[The following information was subsequently received for the record:]

QUESTIONS OF SENATOR INOUYE AND THE ANSWERS THERETO

Question. The Food and Drug Administration (FDA) briefing paper entitled "Parasites in Fish" supports the FDA recommendation that *all* fish that may be consumed raw or rare should be frozen. It appears that the FDA recommendation was not based on adequate information, but on selective interpretation of a few studies.

On what basis did the FDA conclude that *all* fish intended for raw consumption should be frozen?

Answer. FDA does not believe it is appropriate to assume that any particular species is free from parasites, and therefore, safe to eat raw or rare without other precautions. Indeed, studies have shown that even tuna, a species not frequently implicated in such outbreaks, may harbor anisakid larvae.

FDA believes that proper preparation of *all* fish to eliminate parasitic infection is an essential public health measure. Since cooking and freezing are the only controls currently available for protecting consumers against fish parasites, FDA recommends that all fish intended for raw consumption should be frozen.

We have enclosed, for inclusion in the record, letters from the Journal of the American Medical Association documenting anisakis infections from tuna as well as other species.

Question. Does the FDA plan to examine each fish species to determine the probability of parasite infestation if such species is consumed raw or rare? If not, why not?

Answer. It is not feasible for FDA or any other Federal agency to evaluate fish on a species by species basis to determine the probability of parasite infestation. FDA believes that the available control, that is, freezing of fish intended for raw consumption, has been shown to be an effective public health measure to address this concern.

In surveys FDA has conducted of fish species, including tuna, available in commercial markets, some specimens of all species contained larval nematodes of the anisakid group, and some also contained trematodes and cestodes.

The CHAIRMAN. The committee will be in recess briefly so we can make that roll call vote. Then we will continue with these gentlemen and another panel.

[Brief recess.]

The CHAIRMAN. Let us hear from the two gentlemen now from the Food and Drug Administration.

Mr. Benson, you have only answered the questions. It could be that listening to those questions and answers you have some additional comments. I know you are using the same written statement, of course, as the Secretary, but is there anything you would like to say to the committee relative to your agency?

You can see the frustration at the Congressional level. I agree with the Secretary there is no crisis. We have a program, and it is working; People will go out at noon and order a fish lunch or a fish sandwich, and they will live.

On the other hand, we now face new concerns, particularly, if you awakened early this morning and saw the news. One network had a program about red tide, surgical garbage and other types of pollution, from Martha's Vineyard down to Nagshead, North Carolina. I am not going to order a fish lunch today, nor will others if they saw that program. We also will hestitate a little while because we do not think our current system provides tight safety assurances with the 120,000 vessels and with the 120 countries involved. I guess that imports can be regulated effectively because if a country ships in any kind of foul seafood their market is gone. I also understand that a higher percentage of imports are checked over at the National Marine Fisheries Service.

Let me hear from you, Mr. Benson, on why you all are not doing a better job.

STATEMENT OF JAMES BENSON, ACTING COMMISSIONER, FOOD AND DRUG ADMINISTRATION

Mr. BENSON. I have no prepared statement, sir, but I would like to make a few points, and then I will try to answer your question.

I think there are a couple of things that were left over from the earlier portion of the session that I would like to clarify. Perhaps the most important one is I hope no one is left with the impression that the grading services and the quality services that are done by USDA are not paid for by user fees. They, in fact, are paid for by user fees. In fact, much work in the regulatory inspection is also paid for through overtime payment something on the order of between 20 and 25 percent. 22 percent, I think, is the ideal fee.

The CHAIRMAN. Just for the record, when you say "user fee", so there is no misunderstanding, how are those user fees exacted and collected?

Mr. **Benson**. I am not familiar with the innerworkings, but the grading services that USDA does for all agricultural products are paid for by the industry, as far as I understand.

The **Chairman**. By the industry?

Mr. **Benson**. Yes, sir, the safety portion, with the possible exception of some of the overtime payments, just as it is presently paid for by authorized funds for both FDA and NOAA. So I think that is an important distinction, sir, and if you like we can get some material to further clarify that for the record.

The **Chairman**. Very good.

Dr. Knauss, will you now please give us an overview of NOAA's participation?

STATEMENT OF DR. JOHN KNAUSS, UNDER SECRETARY FOR OCEANS AND ATMOSPHERE, NATIONAL OCEANIC AND ATMOSPHERIC ADMINISTRATION, DEPARTMENT OF COMMERCE; ACCOMPANIED BY THOMAS J. BILLY, DEPUTY DIRECTOR, OFFICE OF TRADE AND INDUSTRY SERVICES; NATIONAL MARINE FISHERIES SERVICE; AND JAMES W. BRENNAM, DEPUTY GENERAL COUNSEL

Dr. **Knauss**. Thank you, Mr. Chairman. It is indeed a pleasure to be here with Mr. Benson, who is acting head of FDA. I have brought along with me two colleagues, Mr. Billy and Mr. Brennan. If questions get very difficult, I hope they can help with respect to some of the details.

I have a full testimony that I would like to submit for the record if I may, sir.

The **Chairman**. Yes, your full statement will be included, and you may highlight it as you wish.

Dr. **Knauss**. I will be very brief. The first point I would like to make is that the administration has concluded, as Secretary Sullivan said, that the responsibility for seafood safety and inspection should remain with the Departments of Health and Human Services and Commerce through the FDA and NOAA and that any expansion of the Federal seafood safety program should be directed toward those two agencies.

There has been a lot of legislation introduced with respect to seafood inspection. As you noted when you introduced S. 2228, some 50 bills have been introduced since the 89th Congress with respect to seafood inspection of one kind or another. I think we are getting closer to a workable arrangement.

These bills pose several options with respect to agency jurisdiction. In our view and in the view of the Administration, H.R. 3155 and H.R. 4588 come closest to the Administration position with respect to how that jurisdiction should be handled.

We also note there are some very good ideas in S. 2228, your own bill, sir, includes linkages between the new Federal program and current state programs.

I would like to make a point that there has been a long partnership between NOAA and FDA with respect to NOAA's voluntary inspection program that goes back a number of years. Approximately 10 percent of both domestic and imported fish are now subject to voluntary inspection, and it is the Administration's plan to build upon that voluntary program.

In fact, NOAA and FDA are currently developing an improved joint voluntary inspection program, based upon the Hazard Analysis Critical Control Point concept (HACCP). We which is were directed by Congress to develop a model seafood surveillance program based on the HACCP concept which has the support of industry, all the technical experts and all consumer groups, as I understand it.

We plan to pilot test our new voluntary program which we will have ready in October. Assuming there are no glitches in this pilot test, we expect that we will be ready to implement a full-scale program. It could begin with our present voluntary program, which handles 10 percent or so. We could probably begin that by the first of the year.

It is the Administration's position that this could be expanded to a total mandatory program as controlled by legislation. The details of the divided jurisdiction and how we will do this between NOAA and FDA are found, sir, in the full testimony which I have submitted.

We agree with industry that a full-scale mandatory HACCP program of seafood inspection could enhance the acceptability of seafood. It could enhance the markets.

We also agree with Secretary Sullivan and you that seafood is a safe product. The problems with seafood, to the extent there are any, are primarily with raw mollusean shellfish.

However, I know when I go home to Rhode Island I like to eat clams or what we call Rhode Island guahogs on half shell. I also know that I am taking a small amount of risk when I do so, but I continue to do so. The risk is in the sense that there is occasionally a rogue fisherman who will go into an area where he is not supposed to go, where the waters are polluted and pick up a couple bags of guahogs and somehow slip them into the market. Cooked seafood is one of the safest animal proteins going, including, sir, products from those areas where there has been medical waste washed ashore.

Because the program that we are talking about is in large part, but not totally, a market enhancement program, that is a program to increase the public acceptability of seafood, we believe that user fees are appropriate. We believe the Congress should weigh the relative benefits of market enhancement versus safety and apply the appropriate split to how this program should be financed.

In summary, sir, we believe that there should be a mandatory HACCP-based seafood inspection program. It is the Administration's view that it should be a joint FDA/NOAA program, and that is spelled out in my testimony. We also believe, as Senator Stevens and you have noted, that the primary reason for this program is market enhancement; thus, some level of user fees is justifiable for that reason.

Thank you, sir.

[The statement follows:]

TESTIMONY OF
DR. JOHN A. KNAUSS
UNDER SECRETARY OF COMMERCE FOR OCEANS AND ATMOSPHERE
NATIONAL OCEANIC AND ATMOSPHERIC ADMINISTRATION
U.S. DEPARTMENT OF COMMERCE

BEFORE THE

COMMITTEE ON COMMERCE, SCIENCE AND TRANSPORTATION
UNITED STATES SENATE

MAY 24, 1990

Mr. Chairman and Members of the Committee:

I am John Knauss, Under Secretary of Commerce for Oceans and Atmosphere, and Administrator of the National Oceanic and Atmospheric Administration (NOAA). It is a pleasure to be here today to discuss your proposed legislation on seafood inspection.

The need to strengthen or expand Federal seafood inspection programs and the manner in which this might be done is a topic of concern of many Committees of Congress. It has also been the subject of discussion within the Administration. Agency jurisdiction has been a key issue in debate and discussion. Legislation now before the Congress provides a number of options:

- o Strengthen the existing seafood inspection program within the Food and Drug Administration (FDA) of the Department of Health and Human Services (HHS),
- o Divide the program among two or three Departments, or
- o Establish it in toto elsewhere--either in the Department of Agriculture or in the Department of Commerce (NOAA).

S. 2228 is an example of the latter approach. It would transfer the entire responsibility of seafood inspection to NOAA.

I am pleased that the Administration has concluded that responsibility for seafood safety should remain with FDA and NOAA, and that any expansion of the Federal seafood safety program should be directed only toward these two Agencies.

Of the bills currently being considered before Congress, two House bills (H.R. 3155, with the complementary H.R. 4588), most closely approximate the Administration's position. As an example, H.R. 3155 would continue responsibility for seafood safety with the Secretary of Health and Human Services by strengthening the authorities currently available to FDA. It would also empower that Secretary to enter into agreements with the Secretary of Commerce and other Federal and State agencies to carry out the program in the most efficient manner. Inspections conducted by NOAA would be coordinated with FDA under working arrangements that could be entered into under H.R. 3155. The two agencies have enjoyed a long and successful working relationship.

H.R. 4588, meanwhile, would provide the Secretary of Commerce with authority to establish an appropriate program and standards for fishing vessels.

NOAA and FDA are already developing an improved joint voluntary inspection program under current authorities, as directed in the President's FY 1991 budget. It will be based on the Hazard Analysis Critical Control Point (HACCP) concept and thus designed to enhance our existing statutory seafood inspection programs. The joint FDA/NOAA fee-for-service program will improve the effectiveness of both FDA's current mandatory safety program and NOAA's voluntary inspection program and will gradually introduce the industry to a HACCP-based system that is effective, efficient, and responsive to both industry and consumer concerns, a step necessary to reach the expanded inspection program envisioned by virtually all the legislation introduced to date.

A mandatory HACCP-based seafood inspection program jointly administered by FDA and NOAA, however, would require certain additional statutory authorities for NOAA. All of these authorities are contained in H.R. 4588, and some of those authorities are contained in S. 2228. In fact, we find that S. 2228 contains some excellent and innovative ways for dealing with the unique problems of the seafood industry. Recognition and provision for the relationship that needs to exist between the enhanced Federal mandatory program and equivalent State programs, as discussed under section 8 of S. 2228, are examples of those promising innovations.

Clearly, the collective expertise of FDA and NOAA and the programs they operate constitute an existing national resource. I would like to address those authorities needed by NOAA in the context of the substantive provisions contained in S. 2228. We believe new authorities should:

o Authorize NOAA to prohibit harvesting of fish from areas where the Secretary of Health and Human Services in consultation with the Secretary of Commerce determines a health hazard exists. This issue is addressed in section 7 of S. 2228, which provides authority to NOAA for monitoring of growing and harvest areas and restricting sale of fish products not meeting NOAA standards set under Section 4. We believe the regulation of fish and fish products for public health purposes sold in interstate commerce should continue to be the responsibility of the FDA. However, consistent with its fisheries management responsibilities under the Magnuson Act, NOAA should be granted explicit authority to prohibit or restrict harvesting in areas where and when public health is endangered.

- Authorize NOAA to establish by regulation a HACCP-based inspection program for processing and storage of fish and fish products onboard vessels. This processing vessel program will include mandatory, minimum sanitation standards and provide access to records necessary to document control for HACCP-based principles. The substance of this feature is found in sections 5 and 6 of S. 2228.
- Authorize NOAA to require registration and certification of certain classes or types of vessels where such requirements are needed. Section 6 of S. 2228 allows for registration where HACCP requires it, but does not mandate registration across the board. We support this approach. We do, however, have concerns related to exemptions, which may be allowed under section 13(a)(2) relative to vessels which head, gut, gill, ice or brine. Although such operations may appear simple, abusive handling of certain species may in fact result in consumer illness.
- Establish, in cooperation with FDA, a national consumer education and information program, as contemplated in section 14 of S. 2228.
- Establish civil and criminal penalties for specified violations of prohibited acts. This feature is found in section 11 of the bill.

At the same time, FDA's comprehensive program for seafood safety should serve as the cornerstone for an enhanced Federal regulatory system for seafood; since we view the NOAA and FDA roles as complementary, we would not support the transfer of FDA's current responsibility for seafood safety to NOAA. We believe FDA should receive the additional powers necessary to make a HACCP-based seafood safety program work in H.R. 3155. With the complementary new authorities for NOAA just described, an FDA/NOAA expanded seafood inspection program can substantially enhance the acceptability of seafood in the market place by providing clear governmental assurances of safety and wholesomeness. The governmental assurance will benefit both the industry and consumers of seafood.

It is this marketing aspect of an enhanced seafood program that has led the Administration to conclude that user fees would be appropriate for those regulatory activities whose primary purpose is to enhance marketability rather than to protect public health. Congress should weigh relative benefits of market enhancement and apply appropriate user fees.

I support the Administration's decision on agency jurisdiction, as well. Regulation of seafood requires a knowledge of marine biology and related marine disciplines and a thorough understanding of edible fish species and their habitats. Certain forms of marine toxins, parasites, and microorganisms are unique to seafood. FDA and NOAA have acquired a unique expertise regarding these problems over the course of many years of experience.

A comprehensive knowledge of the complex seafood industry itself is also necessary. FDA's program, which now includes mandatory inspection of processors, shippers, packers, labelers, warehouses, and importers of fish and fish products, as well as the analysis of samples of both domestic and imported products, is targeted to the most likely sources of problems. Similarly, NOAA now provides services such as inspection, grading, laboratory services, and expert consultation to vessel operators, shoreside processors, and even retail food operators.

To support these programs, FDA and NOAA conduct research to improve detection methodologies for contaminants that could potentially affect seafood. Many of the activities in FDA's program require highly specialized knowledge and training not found elsewhere in the Federal Government. Furthermore, both agencies interact with States, other Federal agencies, and foreign countries on a range of activities related to seafood.

FDA pointed out in testimony that no public health problem exists which would justify an upheaval in the current seafood safety program. The range of reported health problems associated with seafood tends to be relatively narrow. Cooked fish is one of the safest animal proteins enjoyed by the American public. What is needed is a scientifically updated and enhanced program, one that provides official assurances of safety and quality to better enable the seafood industry to compete in domestic and foreign markets.

Consumption of raw molluscan shellfish is a major concern, even though less than one percent of all seafood is consumed raw.

The risk associated with raw molluscan shellfish stems largely from pollution of coastal waters, an issue the States and Federal Government must continue to address for a number of reasons. Currently, monitoring the quality of shellfish growing waters is the most viable strategy to protect the consumer. FDA administers the National Shellfish Sanitation Program, a cooperative Federal, State, and industry effort to ensure that waters from which shellfish are harvested are clean, through a relationship with NOAA that is acknowledged in section 4 of S. 2228. NOAA's Fisheries Service closes shellfish beds in Federal waters to harvesting, such as was the case last year when public health risks made it prudent to shut down surf clam harvesting on Georges Bank.

A critical component of water quality monitoring is the ability to detect rapidly contaminants, such as viruses and bacteria. This is an area of ongoing research by FDA and NOAA. The need for such agency research is addressed in Section 15 of S. 2228. In addition, FDA is especially well positioned to take advantage of breakthroughs in seemingly unrelated areas and apply them to seafood. Its own regulatory research base and the proximity of FDA to the sophisticated research programs of its sister agencies within the Public Health Service, primarily those of the National Institutes of Health, aid that effort. For example, FDA's advanced work to develop a gene probe that will be able to detect directly certain viruses and bacteria in the water and in the shellfish themselves is an offshoot of research at NIH.

The effectiveness of inspection is strongly tied to research, analysis, and cooperative relationships with States and foreign countries. Consequently, any legislative proposal that includes a further fracturing of responsibility for seafood safety or would separate inspection from other vital program components is a questionable policy.

We would be pleased to work with you on a bill that would incorporate or modify the key provisions of S. 2228 as the basis for an integrated seafood safety program of FDA and NOAA that deals comprehensively with all aspects of the issue.

Mr. Chairman, this concludes my prepared statement. I will be glad to answer any questions.

The CHAIRMAN. Dr. Knauss, Senator Cohen has attested to the fact that NOAA has had an ongoing voluntary program. How long has that program been ongoing, Mr. Brennan or Mr. Billy? Dr. Knauss has got his lawyers with him now and we have not put them under oath, but I think that they will tell us the truth.

Dr. KNAUSS. I have only one lawyer with me, sir. The other is an expert on seafood inspection, Mr. Billy.

The CHAIRMAN. Yes, Mr. Billy, tell us about the voluntary program. When did you start that?

Mr. BILLY. 1958.

The CHAIRMAN. 1958. So it was in the old Environmental Satellite Services Administration?

Mr. BILLY. It was in the Bureau of Commercial Fisheries, which was at that time part of the Fish and Wildlife Service.

The CHAIRMAN. In the Fish and Wildlife Service before it came over. I see. So you have been doing that since 1958?

Mr. BILLY. Yes, sir.

I have not personally been involved, sir, but our agency has.

The CHAIRMAN. No, I understand.

I understand that you now have a pilot program. What is envisioned in the pilot program, Dr. Knauss? You talk about beginning a new program, and here is a gentleman saying, wait a minute, we have been doing this since 1958. And you are saying, oh, wait a minute, we are going to start in October.

Dr. KNAUSS. We have had a voluntary program of seafood inspection since 1958. The program that we will be starting in October is a pilot of the new joint HACCP program, Hazard Analysis Critical Point Program, which we have been designing based upon a report of the National Academy of Sciences in 1985. And it turns out it is a very complicated issue to develop. As we have been developing it, we have worked with industry, we have worked with the experts in various fields, and we now have a program that is ready to go. We will begin with a pilot test in October. And as I say, assuming that that program works—and we expect it will—we will be ready to expand it to the entire industry, including our voluntary program, which as I noted, includes about 10 percent of all fish products, both imported and exported. We will be able to implement it, if we wish to, on or about the 1st of January, 1991.

The CHAIRMAN. And your testimony is that we should implement it and expand it to a mandatory program?

Dr. KNAUSS. It is our view and the view of FDA, and the view of the Administration, that if we are going to have a mandatory seafood inspection program, it should be on HACCP principles. And yes, we will have the joint voluntary program that should be the basis for the expansion of that program into a mandatory program. Yes, sir.

The CHAIRMAN. Are these views outlined in this booklet that has just come out, "Meeting the Challenge: New Directions in Seafood Inspection?"

Mr. BILLY. That book does contain the basic principles that we will follow, in terms of the approach under a HACCP inspection system. The difference in that book is that Congress mandated that we take a look at how to design a mandatory program. And our initial pilot study and program is going to be on a voluntary basis.

So there are some differences between what the two agencies are planning to implement, first, on a pilot basis in October, and then on a full-scale basis in January, and what that book contains, Sir, because that study is responding to a mandate from Congress.

Dr. **Knauss**. One more point with respect to Mr. Billy's comment, The Administration has decided to go with the pilot program now. We have not yet made a decision that we are going to implement the full program. We are going to stand back and review, and then also talk to industry as to whether we implement a full-scale program as of the 1st of the year. But our present decision is to go with the pilot program.

We will be in a position, we believe, to go with the full-scale program, but we have not yet made the decision to do so.

The **Chairman**. Well, let me try the agricultural approach on now for size. Assume, bam, bam, we sign it, put it into law, and the Department of Agriculture is given the responsibility. Then, I take it that there will be various divisions from FDA and various divisions or facilities, from NOAA that would have to be physically transferred to Agriculture? Am I wrong on that? Tell me what you know to be the case.

Dr. **Knauss**. I guess it will depend exactly on the details of the bill that is passed, sir.

The **Chairman**. Right.

Dr. **Knauss**. I could imagine a bill passed in such a way that it would require some transfer of NOAA facilities and NOAA personnel to USDA. I can also imagine that a bill could be passed in such a way that that would not be the case.

The **Chairman**. Well, I am looking at the Mitchell bill and the Leahy bill, and other that are similar. I cosponsored Senator Mitchell's bill because I am concerned, too, about seafood inspection. I wanted to get something going. But assume the Mitchell bill was enacted into law. Mr. Billy, do you want to elaborate on what offices we have, and, Mr. Benson, you think about yours.

Mr. **Billy**. It would seem to me, based on what is in that bill, that it would require certain components of NOAA be transferred to provide a base of expertise necessary in the seafood inspection area. The bill does call for NOAA to continue a role in the area of water standards under its existing structure. So components of the voluntary inspection program and the laboratories that support it would have to be transferred, and perhaps other parts of NOAA that are involved in looking at safety issues, as it would relate to the consumption of seafood.

There are some other unanswered questions, as well, in that S. 1245 does not address the grading area, which is currently a responsibility of NOAA. Thus, it remains unanswered whether NOAA would continue its grading function and be present in the plants grading products while the Department of Agriculture would be in the plants inspecting for wholesomeness and so forth, or how that would be worked out. The bill does not address this question.

So there are some unanswered questions about that bill.

The **Chairman**. What about it, Mr. Benson?

Mr. **Benson**. My understanding is that the—I do not think any of the bills spell out any formula for how things might be divided up.

They talk more about the basic responsibility and where that responsibility would be.

But if you make the assumption—this is a difficult conflict for me to speak to, but for the safety and the welfare of the country and the people eating seafood, I mean, if the responsibility or part of the responsibility were to go over to USDA, I certainly think that the we cannot just dump this on USDA without any expertise in the area. And they do not have that expertise in the seafood area.

So it would be a fairly simple thing for our three research labs, for example, to be transferred over. What would be very difficult for us is our field—we have about 900 to 1,000 inspectors in the field around the country that do all the inspections, not only for seafood, but foods, as well as the other products that FDA regulates. It would be very—we do not have specific people that do specific inspections, so I am not quite so sure how the expertise there would be transferred to USDA. It has taken a long time to build that.

And likewise, the research that is done, in terms of identifying analytical tools and so on, is also highly integrated, not only into the FDA system, but also into the Public Health Service. So that would be a very difficult problem to address, too.

The **CHAIRMAN**. Senator Cohen, while you were voting, Mr. Benson has attested to the fact that the USDA is on a user-fee basis also. Maybe you want to question him, but the record would show just that. Let me yield to you.

Senator **COHEN**. Well, I was going to ask you to spell that out. You say that it is a specific user fee applied to poultry and beef?

Mr. **BENSON**. No, sir. I offered to look into it and get something back for the record, because I am not that familiar with it. What I am familiar with is that the grading work that is done by USDA is paid for by the industry. As I understand it, it is not supported by appropriations. That was the point that I tried to make.

Senator **COHEN**. Well, do I take the proposition that the less safe something is, the greater the responsibility is for the general taxpayer to pick up the cost?

Mr. **BENSON**. I think that is certainly valid.

Senator **COHEN**. So that the safer you are as an industry, that you have the individual responsibility for paying for inspection by a user fee?

Mr. **BENSON**. I think the point that we were trying to make is that if the industry wants to go beyond what is already being done in the quality area, then that should be the basis for a user-fee supported program. I think the fact that there may be a difference between the way that is operated in meat and poultry now, versus the way it might be operated in seafood, is something that needs to be looked at.

I certainly think it is important to have a level playing field and to have parity. I think that is certainly an important point.

Senator **COHEN**. I am still not sure I understand. On the one hand you are saying if the industry wants to go beyond where it is, in terms of quality assurance or control, that the industry has to bear the cost. If you start with the proposition that seafood is more inherently safe in terms of its record, then it has to then bear a higher cost than its counterparts to come up to a higher level of safety? In other words if you have a lower level of safety you have a greater federal participation as far as taxpayers are concerned?

Mr. **BENSON**. No, I think it speaks well to the Federal Government and whatever portion of the Federal Government is responsible for the safety, and speaks well of the industry if you have a highly safe product. It means that the two are working well together.

I am making a distinction, sir, between safety and quality. And it is the quality that I think we are saying, if additional federal work is required for quality, then that is the portion that should be supported by user fees.

Senator **COHEN**. Well, I did not understand what was meant, Dr. Knauss, you said market enhancement justifies user fees.

Dr. **KNAUSS**. I guess market enhancement is a euphemism for quality control. That is, for grading of values. I agree completely with Mr. Benson on that which addresses public health. Any inspections which address public health we believe the Federal Government has a responsibility to pay for. Anything beyond public health, the question of grading it, whether your beef is good, commercial, prime, et cetera, that should be an industry cost.

Senator **COHEN**. So what you are saying is this whole mandatory inspection program has nothing to do with public health, it has to do with quality control?

Dr. **KNAUSS**. What we are saying is that, insofar as we understand the issue, and I think we do understand the issue, is that seafood, fin fish anyway, cooked fin fish, is considerably safer than is other animal protein, including beef and chicken. The primary reason for the effort to have a new seafood inspection system at this time is because of the industry quality control concern and the public perception that there is an issue of fish safety.

Senator **COHEN**. It had nothing to do with quality, the concerns by the seafood industry has to do with the public perception of safety.

Dr. **KNAUSS**. That is right.

Senator **COHEN**. It has nothing to do with quality control whatsoever? That is not what the seafood industry is concerned about. It is concerned about when we see oil spills, we see chemicals being dumped into the oceans, we see human waste being washed up on shores. It is assuring the consuming public as to the safety features. It has nothing to do with quality enhancement or market enhancement.

I think what has happened here, if I can say so, Mr. Chairman, is we are dancing around the issue of who is going to pay in terms of budget constraints, and saying, well, this is really a quality control issue and therefore it ought to be a user fee and not a tax increase to pay for it. And we are dancing all around the issue to get around that.

We ought to say what is involved here. You have got budgetary constraints. The President is not going to ask for an increased appropriation to cover the inspection, therefore, number one, there is not a safety problem; number two, if you simply want to increase quality control or enhance market share, you better pay for it.

But that is not, in my judgment, the reason why the seafood industry is coming forward. They are concerned of a public perception that the food is not safe.

Dr. KNAUSS. I understand the public perception issue, sir.

Senator COHEN. So it has nothing to do with trying to enhance market share whatsoever. What Senator Stevens is concerned about, and I share his concern, you start talking about imposing additional costs upon the fishing community, and they are going to pass that on in the form of a higher price, so that all those who consume that particular product are going to pay a higher price for it. That is a tax by any other name. That is a tax on those who would consume it. And so what you are doing is you are going to offset—at least put them at a more competitive disadvantage when you start calling it a user fee, as such, when you have in fact a different system for meat and poultry.

So I think we ought to call it what it is. Say that if it is a safety issue or a perception of a safety issue, then we ought to treat the seafood industry the same as we treat beef and poultry.

Mr. BENSON. May I respond to that, Senator?

Senator COHEN. Sure.

Mr. BENSON. I think you have articulated the issue quite well. And I think it is up to the Congress to make that cut. It is not an issue between USDA and FDA and NOAA, it is an issue of how those programs should be administered, and that is a congressional call.

Senator COHEN. The Administration is ducking the issue, basically, by calling it a user fee. Secondly, you point out that neither one of the bills deal with allocating how you are going to divide up the inspection resources, whether it is NOAA, FDA, or whatever. If we did do that in the bill, the Administration would come forward and say that is micromanagement; that is not something that Congress ought to be doing.

So that is why it was deliberately left up to the Administration in terms of how you are going to allocate the resources, as far as inspection is concerned. But I really think what has happened here is we are ducking the issue on exactly what is involved because no one wants to talk about whether it is going to be appropriated or not, because you do not have the budgets to do it.

Dr. KNAUSS. We have made an estimate of what the total inspection would cost. We are working with FDA on the plan that is outlined in my testimony.

Senator COHEN. The pilot plan or the full plan?

Dr. KNAUSS. The total plan.

Senator COHEN. The total plan.

Dr. KNAUSS. And our total estimate, I believe I am right in saying, it is $90 million.

Senator COHEN. And Senator Mitchell said $100 million; $80 million is close enough.

The CHAIRMAN. Very good. Senator Stevens.

Senator STEVENS. Mr. Chairman, I regret I was not here when Senator Mitchell testified, and we are trying to work together. My deepest regret right now is he is not a member of this Committee rather than a member of the other Committee. I really think we have common goals, and obviously his colleague has the same goal that we do, and that is to assure the public that the fisheries inspection system is number one, that there is no question about it that it is safe to consume U.S.-processed fish.

Now, I am still disturbed by the inspection concept that Senator Mitchell has in his bill. I intend to co-sponsor it because I support its objectives, but the concept of putting fisheries inspection jurisdiction in the hands of the Agriculture Committee, people who basically come from agricultural States, and people who are advocates throughout their career of different food chains, I think is wrong.

What I want to seek from this panel is, what is wrong with the bill that the Chairman of this Committee introduced? You all have got an Administration bill. What is wrong with the solution we propose right here?

Dr. KNAUSS. The bill, Senator Stevens, that Senator Hollings introduced is a fine bill. The problem is that it gives all of the responsibility to NOAA, and we believe that what this bill—should spell out is how the inspection should be done—is that it should be a shared responsibility between NOAA and FDA.

Senator Stevens, while you were out of the room I indicated that we have a pilot program which will start in October between NOAA and FDA. I have outlined how jurisdiction should be divided in my formal testimony.

The pilot program is a new, joint inspection program under the so-called HACCP principles, which all the experts agree is how we should go about inspecting seafood. There is a shared responsibility between FDA and NOAA, and if there should be enacted mandatory legislation to inspect all seafood, then it would be the Administration's position it should be an expansion of this effort, which is presently underway and which has been under study for about three years.

That is the only difference, Senator.

Senator STEVENS. As I understand it, he has got the same concept, does he not?

Dr. KNAUSS. Pardon me?

Senator STEVENS. Senator Mitchell's bill involves that same concept.

Dr. KNAUSS. I think it does, yes, sir.

Senator STEVENS. So I think the Chairman's does and yours does, so the type of system is in agreement, right?

Dr. KNAUSS. The type of system is in agreement. The question is, it is a question as to——

Senator STEVENS. Who is going to do it and who is going to pay?

Dr. KNAUSS. Who has the responsibility for it, that is right. Who is going to pay for it is one issue, and how the responsibility is divided is the second issue. The Administration's position with respect to the responsibility is that it should be divided between FDA and NOAA and that the Department of Agriculture should have no role in this. The question of who pays for it is a separate issue.

Senator STEVENS. We increased the fees in airline tickets and the money is building up over in the airport and airways fund. We supported the increased gasoline tax, and charges on batteries and tires, and the money is building up in the highway fund.

Now, what assurance do we have, if we support a concept of payment by our people—now, this is not directly by the consumer. The payment comes from the people who are catching and processing fish directly, as I understand it. If we support that, what assurance do we have you are going to be able to spend that money? It is going to come under the budget system anyway. We could pay all the increased fees we want, and you are not going to get any more money, so why should we talk about funding the way you want to talk about it?

Dr. KNAUSS. I can imagine a way in which one could, for example, have user fees which would indeed come directly into the coffers of those who have to support the program.

Senator STEVENS. Well, I could, too. Let us give it to the Fisheries Management Councils. Put it in there and let them run these systems, and let them run the inspection program, and you can have supervision over their systems. But let them spend the money if we are going to pay it in. If you get it, you are not going to spend it.

Dr. KNAUSS. Sir, if we get a mandate to run a seafood inspection program having to do with food safety——

Senator COHEN. No. Food quality, according to your testimony. Food quality.

Dr. KNAUSS. Food safety and food quality, Senator. I can assure you that at least as long as I am Administrator of NOAA we will enforce it and do what is necessary to carry out that legislation, sir.

Mr. BENSON. I would like to add in answer to what Senator Cohen asked the same question earlier and got a full answer on it, and it—I guess there are two parts to the answer. I think we feel very committed to plowing those funds back into the quality assurance program. I personally feel very committed to that, and I think the assurances that you have is through GAO. I mean, we have got to keep track of those funds. We have been talking about user fees for some time. I think that is simply good fiscal responsibility.

Senator COHEN. GAO says you are—if you will yield—2,000 personnel short now, and the question that Senator Stevens raises, the same one we talked about earlier, is that if you get additional money, you hire additional people, how do we know they are going to be allocated to fish inspection?

Mr. BENSON. By the books we keep.

Senator COHEN. Yes, but I heard Dr. Knauss say you cannot designate which people are inspecting fish versus which are inspecting something else.

Mr. BENSON. Well, I think I said that as well, but it is not on a person-by-person basis. We keep track of resources through the full-time equivalent, the FTE acronym, I am sure you have heard it, where we do keep track of how many people are used in a given program area, and that is how the accounting would be done. I mean, there is no question in my mind that that is—I would feel terribly irresponsible if that were not done. I really would.

Senator STEVENS. I have just one last question.

I have got to tell you, we serve on the Appropriations Committee. You are not going to get any higher budget, no matter how much people pay for this, and you are not going to get any more people.

You are going to have to take them out of your existing programs if you have this responsibility. That is why I think it is foolish to talk about financing this program the way you are talking about it.

We want—my State, I think is going to become the predominant fish-producing area of the world, now. We have such a voracious area, really. Because of our laws that came out of this Committee in terms of moving the foreign fishing fleets out, we have Americanized our fisheries. We are now going to work out with the Soviets a total North Pacific agreement, I hope, and that is going to be—the fish come first. We want the fish to come first in terms of survival, the whole species, and we are going to regulate the fisheries so we can maintain the fish for a long time.

But when we harvest it, we want to maintain the quality. I remember one case in my whole lifetime of a bad can of fish from Alaska—one. The impact of it was felt in the London market. Your people remember that. I have seen dozens of cases of poisoning, et cetera, from chicken and from hamburger, and that never makes the London market. Somehow or other the system reacts, overreacts, to one case. So we have to prevent that one situation, and for the last, I think, eight years, we have done it. Ten years, maybe. The system is working.

An old friend of mine used to say, "If the watch ain't broke, don't send it to the repair shop." I am pleased to put additional security on top of this system, but I am afraid of some of the things I am hearing that will load it down so much that it will break down again. My last question is, how are you going to administer this? Have you looked at the Aleutian Chain recently? There are times that you cannot get inspectors in there for two or three days at a time, and yet people are working three shifts, 24-hours going on. How is this system of inspection going to work? How do you relate, when you have joint responsibility under your suggestion, two different agencies administering this program? Are we going to have two sets of NOAA and FDA people trying to catch the next plane and fighting over one seat that is left on a six-passenger plane going into these small towns?

Mr. **Benson**. No, sir. We do not believe that continuous inspection for seafood is necessary nor appropriate. What we do believe is that under the HACCP program the critical points of a process would be identified. When inspectors are able to come in—and these would either be—they might well be State inspectors. They could be NOAA inspectors. They might be FDA inspectors.

When those inspectors come in they would check to make sure that the records of the processor were in fact in keeping with those HACCP principles. It would not be necessary to have someone come in, if you will, when weather did not permit. The processor would be required to show the records under the Senator's bill—under the bills we are talking about here. Under the voluntary system, that would be done voluntarily. That is the difference, by the way, between the voluntary and mandatory.

So I think that—in principle I think I agree with you. You do not want to overburden the industry with those kinds of inspections. I do not think that is cost-effective either from a safety or from a quality standpoint.

The **Chairman**. Senator Lott.

Senator LOTT. Thank you, Mr. Chairman, and gentlemen. I am sorry I was late, but I have been over on the floor of the Senate, and I know that you have been here quite some time, and obviously you have been asked a lot of tough questions, so I will spare you some of those.

I just think we ought to take a moment to appreciate the fact that we have made such tremendous progress here. There is a general recognition in Congress and in the seafood industry, in NMFS, in NOAA, in FDA, and Agriculture, that in fact we need this system. And that is a pretty good movement from where we have been in the past on inspection of seafood.

So I think this is a positive hearing. I am glad to see the committee getting into it. We are glad to have you here and get your thoughts.

Now, having said that, I am not going to ask a lot of questions, I am just going to read a couple of key points from Senator Mitchell's statement. You know I do not agree with him on a lot of subjects, but in this instance he sums up pretty much how I feel.

He said the Food Marketing Institute has determined that consumer confidence is highest in the Department of Agriculture. USDA has responsibility for the inspection of meat and poultry products, the fishing industries primary competitors. Meat and poultry inspections are funded by the Federal Government at a cost of $400 million annually.

The fishing industry should not be subjected to inspection by a different agency, nor be required to pay for an inspection system while its competitors are inspected under a federally-funded system.

He points out that USDA already has an overseas network of trade officials and inspectors. They already have inspectors that could do the job. According to the GAO report, FDA officials said that there would be 2,000 additional positions needed at FDA to expand seafood inspections.

The President of the National Academy of Sciences Institute for Medicine is quoted as saying that FDA is a demoralized group being asked to do too much with too few resources.

I agree with all of that.

I guess the only question I would have for you is that I personally think that Agriculture ought to the lead inspection agency, with cooperation and coordination with other relevant agencies, including FDA and NOAA. But one question I do have is perhaps who would work with training these inspectors. I do think there is a National Marine Fisheries need to be involved in helping train these inspectors.

Do you all have any comments on that?

Dr. KNAUSS. We already do it, sir. We already train what few USDA people are involved in this business, because we do have the expertise. I would also point out that a number of farmers do indeed grow catfish.

Senator LOTT. What state do most of those grow in?

Dr. KNAUSS. That inspection program, sir——

Senator LOTT. Mississippi.

Dr. KNAUSS [continuing]. Is carried out by NOAA inspectors, not by USDA inspectors. And we also do the inspections with respect to the USDA school lunch program. So, even though there is indeed some fish being grown in Department of Agriculture territory, the fish inspection is done by NOAA, sir, not by USDA.

Senator LOTT. Well, now, you are talking about NOAA. How do you see FDA's role in there? Do you view this as a question between agriculture and NOAA?

Dr. KNAUSS. No, I think it is a question—as I have tried to spell out in my formal testimony, NOAA and FDA have had a program, do have a program. Further, we have a joint, HACCP-based pilot program which we are about to start on the 1st of October between FDA and NOAA with respect to seafood inspection. We are prepared to fully implement that program, assuming that it is a success, and we expect it will be after the pilot program, after the 1st of the year.

And that is a joint program, where the expertise of FDA does what they do best, and the expertise of NOAA does what we do best. We have worked it out. And that would be our position, the Administration's position, with respect to if there is mandatory legislation for expanding that program.

Mr. BENSON. I would like to add to that if I may, sir.

Senator LOTT. Go ahead.

Mr. BENSON. But first I would like to pick up a couple of the earlier points you made. I am not sure of the reference to consumer perception of the agencies, but——

Senator LOTT. With regard to FDA?

Mr. BENSON. Yes, with regard to FDA.

Senator LOTT. Well, that is my perception.

Mr. BENSON. No, you were quoting from Senator Mitchell. I want to point out that in a recent Roper poll, FDA had the highest favorable acceptance rate of any regulatory agency, and that was 74 percent. And I think there were only two or three agencies that had a higher favorable rate. So I do not want to sit here and talk about FDA in that sense, but this is the second time that it has come up in this session, and I feel like I need to speak to it.

As far as the morale issue is concerned, I know the President of IOM, we are all concerned about federal morale and federal employee morale. I do not think FDA's morale is any lower than any other federal agencies. In fact, I think it is higher. And I think the people in FDA are proud, and they are proud of the work they do. And I guess I resent the fact that that kind of statement is implied, and I want to get that on the record.

As far as the 2,000 people, that was a crude estimate on the part of GAO, and I know it was crude because they were quoting us. And it was not a careful analysis. The fact is, we are doing what we call a comprehensive needs assessment right now to try to get a better handle on what kind of requirements really are needed across the board.

But that 2,000 estimate was across the board. It was not only for seafood.

Senator LOTT. What is your estimate on seafood? Have you already given that earlier today?

Mr. BENSON. Well, we talked a little bit about it, but let me pick it up. I think we presently spend about $25 million on our seafood program. The President's budget asks for an additional $9 million for 1991, and that would take it up to $35 million. When you add that to what NOAA has in appropriated funds, you are talking around $50 million. And I think that we agree that if the user-fee program did kick in, an ideal program would be on the order of $80 million or $90 million. And I mean that is rough figures.

The training question that you had, if I may. And I should point out that FDA has been into the HACCP program since 1970. Pillsbury was the first food company that I know of that introduced HACCP. They did it because of the NASA requirements because they wanted to put food in space and they wanted to make sure the astronauts did not get sick, and they came up with a program that, by the way, came out of the aerospace industry, one that FDA is very familiar with, not only in the food area, but also in the medical device area, because it is a concept that is used there for inspections.

Pillsbury pioneered it. FDA has picked it up. We use it in several food areas now. It is the underlying principle of our low acid canned food program, where you are very concerned about such things as heat, making sure that canned foods that are low in acid do not produce botulism and things like that.

And as far as training goes, we presently train state people, not only in the seafood programs, specifically in the shellfish program, which I think is a very strong program in this country, but in retail inspections across the board. The HACCP principles are part of that training program.

As far as where we go to from here, I think we are looking forward to working with NOAA in terms of training whatever inspectors, be they NOAA inspectors, FDA inspectors, we look forward to a lot of state participation in this program. So I would anticipate us doing an awful lot of training of state inspectors as well.

And I think it is interesting that we are going to have to figure out a way to train the industry people. And I would expect that would be done by private enterprise, but I would also expect us to be working closely with private enterprise in that.

Senator **Lott**. What number of anticipated inspectors just for the seafood, if you had this role, do you anticipate? Do you have any idea?

Mr. **Benson**. I think in terms of just the FDA's side of it, which would be in the plans that we have developed with NOAA, we would essentially do a second level inspection or a check if you would of what they had done and what the companies were doing. And so I would see our inspectors, the total FTE is the term that I used earlier, being on the order of a couple of hundred. I do not see a huge program there.

I think that the NOAA inspectors, plus the state inspectors, would far outnumber that. But I will defer.

Senator **Lott**. Well, just in conclusion, I do feel very strongly, personally, that it should be Agriculture working with NOAA, and I think the user fees idea is totally ridiculous, and I hope the Administration would give up its effort in that. Because all you can do is burn up points, and it is not going to accomplish anything.

The **Chairman**. Senator Cohen.

Senator **Cohen**. May I just make the point that the Department of Agriculture does have two functions for meat and poultry: one is the inspection program which is federally funded; and secondly, it is a grading program which is user-fee supported.

The fishing community has no objection to paying for grading, but they do not have any intention for paying for inspection. And what I object to is the notion that somehow what is involved here is trying to quell the problems generated by the appearance of a quality control problem when in fact what they are looking at is a health-related safety program.

And for the Administration to come in and say we have to therefore have a user fee to cover this I think is disingenuous.

The CHAIRMAN. Senator Stevens.

Senator STEVENS. I just want to come back to one thing. And I think Mr. Benson has a point about FDA. You know FDA has such a great reputation up my way, when the FDA—one man walked in and told the industry to destroy its halibut over 150 pounds, they all did it. They just absolutely believed in him that FDA was right. And we have set up a system, I think, that is extremely good.

What bothers me, again, though, is we are back here I think primarily because we have chased the foreign fishermen out of our waters, we are now processing almost 2.5 million metric tons of fish that we did not have available before. When you go into the fast food places and pick up fish tenders or fish sticks or fish fingers or fish sandwiches your chances are three out of four you are eating pollock that came from Alaska waters that previously went by Japanese boats to Korea and were processed there and went into a lot of places in the world market. And we are putting that into our own market.

One billion pounds of that alone is going, I hope before long, into the school lunch program, and will give every school child that has a school lunch eligibility at least one fish lunch per week. It will be good for their health and it will be good for our fishing industry, too.

But the point that bothers me is that, as that happens, as we are building up this industry, it is getting attacked on a basis that never was applied to the foreign supply of fish that has been coming into this country since World War II. It is the same fish. We are now processing it and putting it into the system. And more and more people are thinking about more and more ways to regulate it coming in, in my opinion.

Now how can you assure my fishermen that all of this plan, whether it is your plan or the Chairman's plan, or Senator Mitchell's plan, is not going to mean that there are more people standing there at the pass and preventing him from processing this fish before it does go bad? That is the thing that bothers me.

Are you going to interrupt the flow of fish and the processing with these systems? Do you think it will, Dr. Knauss, Mr. Benson?

Dr. KNAUSS. I do not see any reason why it should, sir. And I guess I would point out that the HACCP plan that we have discussed has the backing of industry. So we have been working with industry in the development of this plan, and I like to think that it will not raise any of the issues or the problems that you have raised.

Mr. BENSON. I think it should speed it up. If it does not speed it up, then we have failed.

Senator STEVENS. Okay, thank you.

The CHAIRMAN. Very good. The committee is indebted to all of you here in this first panel this morning. We very much appreciate it. And as we go for the second vote, will the second panel please come up, Ms. Bloom, Mr. Iani, and Mr. Ken Moore. You all come forward, and we will be back momentarily after this vote.

Senator STEVENS. Mr. Chairman, would you yield just a minute?

The CHAIRMAN. Yes, sir.

Senator STEVENS. My good friend, John Iani is coming here just about the time I have got to leave. I do have to go to a meeting, and I am sorry I am not going to be able to present him for the committee, but I want you to know that my youngest son runs one of his boats. So, you treat him very kindly.

The CHAIRMAN. Oh, is that where he is?

Very good.

Mr. BENSON. Thank you very much. [Recess.]

The CHAIRMAN. We welcome each of you. Your full statements will be included in full in the record, and you can highlight them as you wish.

Ms. Bloom.

STATEMENT OF ANNE BLOOM, ON BEHALF OF PUBLIC CITIZEN

Ms. BLOOM. Thank you, and good morning. I am representing Public Citizen, which is a national consumer advocacy organization. We appreciate the opportunity to testify. I was asked to provide a consumer perspective on the need for mandatory fish inspection. We have joined several labor and consumer groups in collaborating on a joint statement on proposed mandatory fish inspection legislation which I would like to have included in the record, if that is possible.

The CHAIRMAN. It will be.

Ms. BLOOM. Thank you.

I will begin by noting that America's consumption of fish and seafood is rising. At the same time, numerous studies link consumption of adulterated fish with serious human illness. Despite this, the Nation has no mandatory Federal seafood inspection program. The authority to regulate fish contamination lies with the FDA, but the FDA has seriously failed to provide the strong regulation needed to give the public the assurance of safety to which we are entitled. For example, under its present regulatory scheme FDA inspects less than 1 percent of domestic seafood products each year.

Despite FDA's shortcomings, Public Citizen favors keeping authority for fish inspection with the FDA. We hold this view because we believe that the focus of a mandatory fish inspection program should be protecting public health, and this is clearly the historical mission of the FDA. We have serious concerns about transferring responsibility for fish inspection to the USDA whose mission of promoting the sale of agricultural products could potentially conflict with protecting public health.

For the same reasons, giving primary responsibility to the Department of Commerce would also be inappropriate. This being said, we would not oppose strong fish inspection legislation that places administrative authority with another agency.

What should a public health-based fish inspection program look like? We are aware that there is considerable interest in applying a Hazard Analysis Critical Control Point, or HACCP, type of approach to a Federal fish inspection program. Our understanding of the HACCP approach is that it would permit self-regulation by the industry with greatly reduced Federal oversight. We are skeptical that industry and the relevant agencies have the commitment necessary for making it work. We are also concerned about setting a bad precedent for inspection of meat and poultry which currently requires continuous inspection at slaughter.

If fish is to be inspected differently from other flesh foods, than the public health rationale for doing so should be clearly stated. Also, a different inspection label indicating less than continuous scrutiny should be used.

HACCP is essentially a program of contamination prevention. It will not be successful without strong regulatory oversight and enforcement. This means that HACCP plans should be developed under Federal regulatory direction, including specific requirements on sanitation for fish processing, handling and transportation. Legislation should specify that the HACCP approach applies to the whole chain of food production from source waters to the consumer's plate. Verifying inspection should be random and unannounced. Mandatory microbiological and chemical standards for contaminants and intensive sampling are also integral parts of a good program.

To assist with enforcement, industry recordkeeping should be open to public access as it is with other public health programs. We think that the strongest enforcement program would make use of State resources and also permit enforcement of laws where the Federal governing agency has failed. Federal standards should be a floor for states and not a ceiling.

Finally, as implementation of HACCP programs shifts the bulk of inspection responsibility over to the industry, we think it is absolutely essential that industry inspectors be assured that reported violations will not cost them their jobs. Whistleblower protection is a critical piece of mandatory fish inspection legislation.

In closing, we are aware that there are a number of mandatory fish inspection bills that have already been introduced in the Senate. We are currently unable to support any of these bills, but the legislation recently reported out of the Senate Agriculture Committee includes many pluses for consumers. Unfortunately, it does not include whistleblower protection.

We strongly believe that it would be a serious mistake to pass fish inspection legislation that gives consumers the impression of protection without the enforcement tools it needs to back it up. For this reason, we will oppose fish inspection legislation that fails to include whistleblower protection.

That is all I have to say. Thank you.

[The statement follows:]

STATEMENT OF ANNE W. BLOOM ON BEHALF OF PUBLIC CITIZEN

Good morning. My name is Anne Bloom, and I am a staff attorney with Public Citizen's Congress Watch.[1] Thank you for this opportunity to testify on the important issue of mandatory fish inspection.

Public Citizen has a long-standing interest in promoting and enforcing laws designed to ensure the safety of the nation's food supply. In past years, Congress Watch has worked for the reform of laws governing pesticide residues in food, and Public Citizen has brought cases seeking a ban on Alar, more stringent regulation of aflatoxin, and a ban on cancer-causing color additives.

Public Citizen has joined a number of other consumer groups, environmental organizations and unions in calling for mandatory fish inspection legislation. Several labor and consumer groups have collaborated on a joint statement on "Proposed Mandatory Fish Inspection Legislation", which is attached.

I. Mandatory Fish Inspection is Necessary to Protect Public Health.

America's consumption of fish and seafood is on the rise.[2] At the same time, numerous studies link consumption of adulterated fish with serious human illness.[3] Each year, thousands of Americans become ill -- and in some cases die -- from eating contaminated seafood.

---

[1] Congress Watch is the lobbying arm of Public Citizen, a national consumer and environmental advocacy organization founded by Ralph Nader in 1971.

[2] Per capita consumption of seafood was 15.7 lbs. in 1989, compared to 12.7 lbs. in 1980, according to the Economic Research Service of the Department of Agriculture.

Seafood contamination is caused by a variety of factors (e.g. polluted source waters, faulty harvesting practices, unsanitary processing conditions). Because most fish are still harvested in the wild, they are continuously exposed to an indeterminable number of chemical pollutants in the environment around them. Among the most hazardous compounds are heavy metals (e.g. lead, mercury, and arsenic), industrial chemicals (e.g. PCB's) and pesticides (e.g. DDT). These substances accumulate in the fatty tissues of the fish, posing potentially significant health risks to consumers. Excessive exposure to these toxic chemicals can cause neurological disorders, birth defects, kidney damage, impaired mental development and cancer.

Another source of concern is the possibility of biological or "natural" contamination. Pathogens from sewage and poor processing procedures open the door to such diseases as botulism, cholera and Hepatitis A. Furthermore, some species of finfish produce "natural toxins" which are harmful to humans when eaten (e.g. ciguatoxin). Though reactions to these contaminants vary, they include diarrhea, nausea, chills, fever, abdominal cramps and -- in some cases -- death.

---

[3] See, for example, the testimony of Dr. Michael R. Dicks, Department of Agricultural Economics, Oklahoma State University, before the House Agriculture Committee, Department Operations, Research and Foreign Agriculture Subcommittee, on February 7, 1990. Mr. Dicks' testimony summarizes some of the available data.

II. Current Inspection of Fish is Inadequate.

The authority to regulate fish contamination lies with the Food and Drug Administration (FDA). Under the Food, Drug and Cosmetic Act, the FDA has the authority to regulate contaminants of fish to ensure a safe and wholesome food supply. Yet FDA has seriously failed to provide the strong regulation needed to give the public the assurance of safety to which it is entitled.

At least part of the FDA's problem is a lack of resources. The second half of the equation is administrative malaise. Under its present regulation scheme, FDA inspects less than one percent of domestic seafood products each year.[4]

Another problem involves the absence of specific tolerance levels for contaminants in fish. Despite having the authority to regulate allowable limits for contaminants like mercury and lead since 1938, the agency has generally relied on informal enforcement guidelines to ensure that fish is not tainted. These so-called "action levels" are of limited utility to FDA's current inspection program: only a handful of hundreds of potential "action levels" have been set, and none of them has the full force of law.[5]

---

[4] In 1986, the FDA analyzed six pounds of fish for every million pounds eaten, substantially less than one percent (See Lefferts, Lisa Y., "The Truth About Seafood," Garbage Magazine, September/October 1989, p. 30.

[5] For a discussion of the inefficacy of these "action levels" for enforcement purposes, see Young, Frank E., Commissioner, Food and Drug Administration, Statement before the Committee on Energy and Commerce -- Subcommittee on Health and the Environment, September 15, 1989, pp. 32-34

Other federal agencies and programs have also been involved in efforts to ensure the safety of seafood: The National Oceanic and Atmospheric Administration (NOAA) of the Department of Commerce operates a voluntary inspection service for processors that desire a federal seal for marketing purposes; the Environmental Protection Agency (EPA) cooperates with the FDA in setting contaminant limits for pesticides; and State regulatory officials, along with federal agencies and the shellfish industry, have a formal Memorandum of Understanding with the FDA to run the Interstate Shellfish Sanitation Conference (ISSC).

Some would seek to move responsibility for fish inspection to the United States Department of Agriculture (USDA), which already operates the nation's meat and poultry inspection program. Public Citizen favors keeping authority for fish inspection with the Food and Drug Administration. The focus of a strong mandatory fish inspection law should be protecting public health; this is clearly the historical mission of the FDA. Because of this history, agency scientists have superior expertise in identifying and detecting food contaminants. We have serious concerns about giving responsibility for fish inspection to the USDA, whose mission of promoting the sale of agricultural products could potentially conflict with protecting public health.[6] For the same reasons, transferring responsibility to the Department of Commerce would be inappropriate.

---

[6] A 1978 study of food regulations by the Senate Government Affairs Committee (prepared pursuant to S.Res. 71) documented the potential for conflict of interest and recommended that all food safety functions be transferred to the FDA ('Study on Federal Regulations," Volume 6, Chapter 4).

Even though we favor leaving authority for fish inspection with the FDA, we would not oppose strong mandatory fish inspection legislation that placed administrative authority with another agency. Nevertheless, we do believe strongly that the FDA should be responsible for setting contaminant standards.

III. Elements of Mandatory Federal Fish Inspection

A. HACCP Approach is Problematic

There is considerable interest in applying a Hazard Analysis and Critical Controls Points (HACCP) approach to a federal fish inspection program. A HACCP system attempts to identify the risks associated with a particular product and the points along its production cycle where those risks are most likely to be introduced or multiplied. Monitoring and verification procedures measure and ensure the system's effectiveness. Our understanding of the HACCP approach is that it would permit self-regulation by the industry with greatly reduced federal oversight. While there is a certain economic attraction in moving the bulk of the inspection cost burden to industry, we are skeptical that industry and the relevant agencies have the commitment necessary for making it work.

Additionally, it is likely that insufficient information exists to apply the HACCP approach effectively for fish inspection. The first step in a HACCP approach is to analyze the hazards of a particular product. In the case of fish, it would be important to know how much people eat of the frequently contaminated species and what level of exposure to different contaminants presents risks. Much of this information is currently unknown.[7]

We are also concerned about setting a bad precedent for inspection of meat and poultry -- which currently requires continuous inspection at slaughter. If fish is to be inspected differently from other flesh foods, then the public health rationale for doing so should be clearly stated. Also, a different inspection label --indicating less than continuous scrutiny -- should be used for fish inspected under the HACCP approach.

B. HACCP Based Inspection Needs Strong Federal Oversight

If a HACCP based approach were adopted for federal fish inspection, safeguards should be written into legislation to ensure that the program adequately protects public health. HACCP is essentially a program of contamination prevention. A public health based program needs regulatory oversight to verify that contaminated food is not entering the marketplace.

1. Federal Review of HACCP plans.

HACCP plans should be developed under federal regulatory direction. Regulatory instruction should include specific requirements on sanitation for fish processing, handling, and transportation. Once developed, HACCP plans should be federally certified with regular and automatic re-review.

---

[7] Benson, James S., Acting Commissioner on Food and Drugs, Food and Drug Administration, Testimony before the House Committee on Agriculture -- Subcommittee on Department Operations, Research and Foreign Agriculture, February 7, 1990, p. 15.; and Young, Frank E., Commissioner, Food and Drug Administration, Statement before the Committee on Energy and Commerce -- Subcommittee on Health and the Environment, September 15, 1989, pp. 35-37.

2. Frequent and Comprehensive Inspection.

Strong mandatory federal fish inspection legislation should also specify the frequency and extent of federal oversight inspection. Legislation should specify that the HACCP approach applies to the whole chain of fish food production -- from source waters and harvesting vessels to processing establishments to the consumer's plate. Both industry monitors and federal inspectors should undergo training and receive outside certification of their knowledge of HACCP principles. In many cases, industry monitoring might need to be continuous and this could be established through regulation. Federal inspection should be random and unannounced but the frequency could vary depending on the history of the firm's compliance, production amount or the public health risks associated with particular commodities involved. A poor compliance history or a high worker injury and disease rate should trigger increased inspection, as these are reasonable predictors of food safety problems.

3. Microbiological and Chemical Standards.

Mandatory microbiological and chemical standards for fish contaminants are an integral part of a mandatory fish inspection program. These standards help to identify the health risks involved, focusing contamination prevention strategies. While the goal may be zero contamination, standards establish a mandatory safety level which cannot be exceeded. Intensive sampling will be necessary to prevent fish with unhealthful levels of contamination from entering the market and to monitor the success of the contamination prevention strategy. FDA has indicated in testimony that it may be impossible to set standards for certain microbiological contaminants or to detect violations.[8] If the agency can't determine a safe level of contaminant exposure or lacks the technology to detect particular contaminants, consumer warning labels and direction for proper handling should be required. At the very least, no federal seal should be awarded. Finally, all standards should be subject to periodic re-review.

4. Public Education Program.

Since many food-borne illnesses result directly from abuse or improper preparation by the consumer, a consumer education program could go a long way towards reducing the number of fish-related poisonings. Federal funding should be provided for such a program.

5. Imports Treated With Equal Scrutiny.

Imports represent perhaps two-thirds of all seafood consumption in the U.S. They should be held to a standard that is at least substantially equal to that which is required domestically. Regular inspection of foreign facilities and intensive sampling of imported products are critical. Finally, because it may be difficult to require or verify a HACCP approach in foreign facilities, stepped up sampling of imports is necessary.

C. Enforcing HACCP Programs.

The federal government has an important role to play in ensuring that HACCP programs are fully complied with and in deterring non-compliance. The strongest enforcement program would make use of state resources and permit citizen enforcement of laws where the relevant governing agency has failed. Existing state programs need not be re-invented, but states should be held to minimum federal standards to bring all consumers the same degree of protection and confidence, regardless of the state in which they live. The enforcement of federal minimum standards is particularly important in states which may feel economic pressure to adopt lax regulation. The federal government could certify state programs with automatic revocation when states fail to implement the federal minimum standard.

---

[8] See Young, pp.35-36.

To assist with enforcement of sanitation, processing and contaminant regulations, industry record-keeping should be open to public access as it is in other public health programs. These records can be used to trace the source of contaminated fish, to prevent harvesting from contaminated areas and to better control sources of contamination before marketing.

Plant employees responsible for implementing HACCP programs should be protected when they report illegal activities that may be harmful to public health. Currently only federal employees are covered by whistle-blower laws. As implementation of HACCP programs shifts some of the inspection responsibility over to industry, it is essential that industry inspectors be assured that reporting violations will not cost them their jobs.

Finally, violators of the minimum sanitation and contaminant standards should be subject to both civil and criminal penalties with publication in the federal register and local newspapers of general circulation.

IV. Specified Timelines and Adequate Funding Are Critical

Experience with other food safety programs teaches that adequate funding is critical to the success of a mandatory fish inspection program. We find it impossible to fairly estimate the costs but would support $75 million dollars as a good starting point. This money should come from general federal funds, as this represents the least regressive tax option. We would oppose the use of federal funds for the development or inspection of cosmetic standards that have no bearing on public health.

It is also hard to predict the amount of time necessary to develop standards and implement a mandatory inspection program. Despite this difficulty, it is important to write tight deadlines and compliance dates into the law to ensure that the governing agency acts with due speed in implementing the program.

V. Legislation Currently Under Consideration Would Not Give Consumers the Assurance They Deserve

A number of mandatory fish inspection bills have already been introduced in the Senate. At this writing, Public Citizen is unable to support any of these bills. Legislation introduced by Senators Mitchell and Leahy was recently reported out by the Senate Agriculture Committee. While this bill includes many pluses for consumers, it does not include whistleblower protection. Effective enforcement of standards, in the absence of continuous inspection, is not possible without adequate protection for workers that report health and safety violations. We believe that it would be a mistake to pass fish inspection legislation that gives consumers the impression of protection without the enforcement tools necessary to back it up. Public Citizen will oppose fish inspection legislation that fails to include whistleblower protections.

It is clear that consumers care deeply about the safety of the food supply. Mandatory fish inspection is an important part of an effective national food safety strategy. Current regulatory programs have failed to give the public the assurance of safety to which it is entitled. What is needed is a comprehensive federal regulatory policy that ensures to the maximum extent possible that health-threatening bacteria and chemical residues do not contaminate fish. We urge Congress to act quickly to enact and fully fund a mandatory federal fish inspection program.

STATEMENT BY CONSUMER AND LABOR ORGANIZATIONS ON PROPOSED MANDATORY FEDERAL FISH INSPECTION LEGISLATION

The undersigned groups strongly support legislation to create a mandatory federal fish inspection program, the goal of which is to protect the public from disease arising from the consumption of contaminated fish, shellfish and other seafood products.

THE NEED FOR MANDATORY FEDERAL FISH INSPECTION

Fish and shellfish consumption has increased steadily over the past few years. Americans eat over three billion pounds of these products each year. As consumption has risen, so has the risk of contracting serious illness from fish and shellfish, especially raw shellfish.

Despite the obvious risk to consumers, fish and shellfish are the only flesh foods not subject to a comprehensive, mandatory federal inspection program.

The Present Voluntary Program Does Not Protect Public Health

The voluntary inspection and grading program operated by the National Marine Fisheries Service of the Department of Commerce and paid for by corporate users is designed primarily to promote the marketing of fish products and not to protect public health.

The Food and Drug Administration inspects seafood in interstate commerce, as part of its general authority to assure that food is safe, wholesome and not misbranded or deceptively packaged. The FDA program is woefully inadequate, inspecting a seafood processing establishment only about once every four years and testing only about 2,000 samples of seafood each year.

Fish Producers Gain an Unfair Competitive Advantage

The absence of mandatory publicly funded federal fish inspection creates competitive inequities as well as public health problems. Red meat, fish and poultry are, to some extent, competing products. Red meat and poultry processors incur certain costs in complying with federal inspection. While these costs are a small price to pay to assure public health and consumer acceptance of their products, they add up to an unfair pricing advantage for fish producers who do not have to meet inspection costs.

Growing Public Concern Spurs Drive for Mandatory Fish Inspection

Public concern about the wholesomeness of fish products may have been responsible for a drop in finfish consumption last year. As a result, both Congress and the fish industry have begun to seek a mandatory federal inspection program. Consumer and labor groups welcome this change in attitude.

THE GOAL: IMPROVED PUBLIC HEALTH PROTECTION

However, enactment of a taxpayer-supported program that is designed to promote seafood marketing is shortsighted and unacceptable. Therefore, the undersigned organizations will oppose any fish inspection program that does not provide improved public health protection. Because all existing food inspection programs have major deficiencies, Congress should use the opportunity presented by creation of a fish inspection program as a model to set a new, higher standard for food inspection.

ELEMENTS OF AN ADEQUATE PROGRAM

We believe the following provisions are essential to an effective fish inspection program:

* Requirement that such a program be mandatory and publicly funded.

* Standards limiting microbiological and chemical contamination in fish and shellfish. Harmful bacteria, including c. botulinum and Vibrio cholera-01, and chemical residues -- such as mercury, lead, cadmium, arsenic, PCBs, DDT and dioxins -- are frequently found in fish and shellfish.

* Certification and frequent inspection of fish harvesting vessels to assure compliance with acceptable sanitation, icing and handling standards.

* Substantially improved monitoring of source waters to prevent the harvesting of fish and shellfish in contaminated waters. The present, state-based program has not successfully prevented seafood products from being taken in heavily contaminated waters.

* Requirement that imported fish meet the same standards as domestic fish.

* Random and unannounced inspections of boats and processing plants.

* Public access to records of federal inspection of harvesting vessels, processing plants, and source waters.

* "Whistleblower" protection for industry employees who report illegal acts that may threaten public health to federal enforcement authorities.

* Establishment of both civil and criminal penalties for violations.

* Publication in the Federal Register of the names of fish producers and processors who violate the law.

* Strict requirements governing the frequency and intensity of inspection. Meat and poultry are subject to continuous inspection during slaughter. No one has provided a public health justification for treating fish differently. The presence of a federal inspector in a plant or on a harvesting vessel at all times sets a standard for safety and sanitation that cannot be achieved at the present time in any other way. Sophisticated standards and tests may be developed in the future that would obviate the need for continuous inspection, but such standards and tests are not available now.

At a minimum, fish inspection legislation should require inspectors to visit plants no less than weekly until each plant establishes that it meets federal standards and is not a threat to public health.

* Consideration of occupational health and safety records in determining the frequency and intensity of inspections. Any fish processor whose practices result in a high injury and/or illness rate among its workers, as reflected in the records of the Occupational Safety and Health Administration, has already demonstrated a prima facie lack of concern for sanitation and safety that demands close scrutiny.

Many injuries to workers in these plants are the result of a failure to comply with basic sanitation and safety standards. If OSHA records indicate such is the case, the enforcement agency should be required to increase the frequency and intensity of inspection in order to insure that these problems are not contributing to a public health threat.

PENDING FISH INSPECTION BILLS

Several fish inspection bills have been introduced in Congress in recent months. They enjoy the sponsorship of leading members of Congress, including the Senate Majority Leader, the Chairman of the Senate and House Agriculture Committees, and the Chairmen of the House Energy and Commerce Committee and its Health Subcommittee.

The bills vary widely in their commitment to public health protection. Several are primarily designed to promote fish products, not protect human health. Two bills include most of the provisions we believe are essential to a system that can offer substantial public confidence in the safety of fish. They are S. 1983, introduced by Chairman Patrick Leahy of the Senate Agriculture Committee and H.R. 3481, introduced by Representative Dan Glickman.

- H.R. 3155, introduced by Chairman John Dingell of the House Energy and Commerce Committee and Chairman Henry Waxman of the Health Subcommittee of Energy and Commerce include several of the necessary requirements, especially standard setting provisions; civil and criminal penalties for violations; and unannounced, random inspections.

None of the bills include a justification for inspecting fish less vigorously than meat and poultry, and none include provisions that require consideration of plant health and safety records in determining the level of inspection. They should.

WHICH FEDERAL AGENCY IS BEST PREPARED TO ADMINISTER A HEALTH-BASED FISH INSPECTION PROGRAM?

The bills also differ in assignment of responsibility for administration of a fish inspection program.

Both S. 1983 and H.R. 3481 divide responsibility for fish inspection among several agencies. The bills assign overall responsibility to the Department of Agriculture, but also include roles in standard setting for the Food and Drug Administration and the National Academy of Sciences and, in monitoring of harvesting waters, for the Department of Commerce.

H.R. 3155 assigns primary responsibility to the Food and Drug Administration.

Neither the FDA nor the USDA has a record in food safety enforcement that would reassure consumers.

The Food and Drug Administration, U.S. Department of Health and Human Services

FDA is the nation's primary food safety agency and the primary mission of HHS is improving and protecting public health and welfare. Both the agency and the Department are staffed with experts in human medicine and public health.

However, FDA has never been provided the resources necessary to conduct an adequate food safety program. In fact, FDA's budget has actually diminished over the past decade, even though its responsibilities have increased. The Center for Food Safety and Applied Nutrition, has been especially hard hit by these budget cuts, and its food inspection program is woefully inadequate. At the present time, FDA staff inspect food processing operations only every three years and, in its present fish inspection program, only every four years.

Further, the Food, Drug and Cosmetic Act does not include a number of enforcement powers necessary for adequate food inspection.

Finally, the agency has been under severe attack for poor administration of its programs. It failed to detect a major scandal in its generic drug program. It has refused to deal with the burgeoning problem of misleading health claims for food, failed to regulate approval of animal drugs in a manner that effectively protects human health, suppressed available tests that can detect unsafe drugs that are contaminating the milk supply, refused to prohibit the use of antibiotics in animal feed, and failed to reduce pesticide contamination in foods.

Food Safety and Inspection Service, U.S. Department of Agriculture

USDA has a large staff and substantial financial resources devoted to inspecting meat and poultry. There is, however, little in the Department's record, especially during the past decade, that justifies giving it additional responsibility for protecting public health.

The Department is more of an apologist for the agribusiness industry than a watchdog for public health. It has refused to take effective action to reduce salmonella contamination of poultry, and supported continued abuse of pesticides and opposed congressional efforts to restrict dangerous pesticides. The Secretary of Agriculture has taken the lead in defending continued use of hormones in meat production despite the fact that the European Community has banned them.

There are a number of reasons why USDA consistently fails to act to protect public health.

First, the Department has an inherent conflict of interest in administering public health oriented programs, especially inspection programs. Congress has directed the Department to promote the use of agricultural products and its institutional bias is to protect agriculture. When a choice must be made between its conflicting responsibilities, USDA almost always opts to protect products and producers, not consumers and public health. The Food Safety and Inspection Service, which would administer a USDA based fish inspection program, is under the direction of the Assistant Secretary who is also charged with marketing food.

Second, the Food Safety and Inspection Service has no clear mandate to protect public health and no public health criteria for its present programs. The agency operates without adequate scientific data on public health, is oriented toward animal health and has virtually no human health experts on its staff. None of the agency's top officials has a degree in public health or human medicine.

Third, according to the National Academy of Sciences, the agency is too close to the regulated industry and too sensitive to its concerns.

The agency's failure to reduce salmonella contamination in both broiler chickens and eggs is one example of this problem. Food-borne salmonellosis is a serious public health problem, costing the nation thousands of lives and millions of dollars in medical bills and lost income each year. The problem is increasing. The Centers for Disease Control report that eggs and improperly cooked, contaminated poultry are the major sources of increased salmonellosis.

USDA's own studies show that over one-half of all poultry is contaminated with salmonella, but the Department has deferred to the broiler industry and rejected steps that would reduce the problem. Despite this record of failure, FSIS has proposed to gut cattle inspection the same way it reduced poultry inspection, through a "streamlined inspection system" that has been associated with increased contamination of poultry.

The Wall Street Journal reported January 9, that despite the fact that salmonella enteritidis in eggs has reached epidemic proportions, the USDA refused to implement a mandatory egg testing program because it would strain the Department's budget and because "the Department doesn't have any authority to act if the disease doesn't sicken or kill hens."

Finally, there are reports that the Secretary of Agriculture has indicated he will use the precedent of less than continuous inspection for fish to reduce the intensity of meat and poultry inspection.

CONGRESS SHOULD ACT QUICKLY TO MEET THE NEED

It is imperative that Congress act to institute an effective mandatory federal fish inspection program. Such a program should improve public health protection, not set a precedent for diminishing the quality of meat and poultry inspection.

We have outlined the basic elements that are essential to gaining our support and the public's confidence. In resolving the issue of which agency will have primary responsibility for adminstering fish inspection, Congress should begin by remedying the problems that presently would prevent either agency from performing adequately.

We will vigorously support such a program and just as vigorously oppose any legislation which fails to provide necessary public health protection and adequate enforcement.

Center for Science in the Public Interest/Americans for Safe Food
Consumer Federation of America
Consumers Union
Government Accountability Project
National Consumers League
Public Citizen
Public Voice for Food and Health Policy
American Federation of Labor and Congress of Industrial Organizations
Food and Allied Service Trades Department, AFL-CIO
United Food and Commercial Workers International Union

February 2, 1990

The CHAIRMAN. Mr. Iani.

STATEMENT OF JOHN IANI, EXECUTIVE DIRECTOR, PACIFIC SEAFOOD PROCESSORS ASSOCIATION

Mr. IANI. Thank you, Mr. Chairman. My name is John Iani, and I am the President of the Pacific Seafood Processors Association, PSPA. I am out from Seattle to testify on this important issue. PSPA is an association of the largest seafood processing companies operating in the States of Oregon, Washington and Alaska. Our members process everything from king crab to arrowtooth flounder.

Approximately 80 percent of the value of seafood products originating in the North Pacific is accounted for by our members. Our members' headquarters and corporate operations are located in Seattle, but our processing plants are located from Astoria all the way around to Akutan Island in the Aleutian chain.

Ms. Bloom's testimony really is the reason why I'm here today. We have been quietly operating in the Northwest, producing what we believe to be excellent consumer product seafood, but because of a few small occurrences in the industry and the public consumer problems that have arisen from them, we believe it is important for us to appear here before you to tell you that we are prepared to participate in any Federal mandatory inspection program that you devise for us. We are that confident that we will be able to convince the public that our seafood is safe.

So as a result of what we think to be distorted public opinion on the quality and safety of U.S. produced seafood, we are here to testify in favor of a Federal mandatory inspection program. There are, however, some points we would like to see that program contain.

One, it should be Federally funded.

Two, we believe it needs to be based on the HACCP or Hazard Analysis Critical Control Point monitoring. It should not be continuous because we believe it cannot be continuous. One of our plants in Akutan is currently producing 1 million pounds of pollack per day. To state that you can analyze each particular pollack as it comes by on the belt is ludicrous.

It should be stringent in its coverage of imported products, Mr. Chairman. We believe that once an imported product comes into the United States, it gets lumped in with our U.S. produced product as well, and, therefore, its quality or lack thereof is tied to our quality.

It should be under the authority of a single Federal agency, and I have to say that our members are sort of divided on that. I know that is a critical question that has come up today before the committee, but we simply have not formed a consensus. Some of our members support Ag; some of our members support FDA; but we believe it should be a single Federal agency.

On the sideline, we believe, specific to our region, the North Pacific, any program should include the ongoing and very successful canned salmon control plan which is currently administered by the Food and Drug Administration.

In closing, though, Senator Hollings, I would like to state that our industry has enjoyed a very longstanding and good working relationship with the members of this committee and with the members of the House Committee on Merchant Marine and Fisheries. We feel that because of this good relationship and because of your expertise regarding seafood issues in general that any legislation dealing with seafood inspection should be given a thorough review by both your committee and the committee in the House.

We feel it is critical that the members of Congress who know our industry and who have worked with our industry have a major role in crafting any seafood inspection program and have a continuing role in its implementation.

My statement has been included in the record, and I would be happy to respond to any questions. Thank you.

[The statement follows:]

STATEMENT OF L. JOHN IANI ON BEHALF OF PACIFIC SEAFOOD PROCESSORS ASSOCIATION

Good morning. My name is L. John Iani and I am the President of the Pacific Seafood Processors Association (PSPA). PSPA is a trade association of companies involved in seafood processing in the states of Oregon, Washington and Alaska. Its members firms process a variety of products for the retail and wholesale trade, including salmon, crab, halibut and a variety of species of groundfish. Approximately 80% of the value of seafood products originating in the Northwest and Alaska is accounted for by members of PSPA. Although the headquarters of the Association and most of the member companies is located in Seattle, the majority of the processing plants are in the state of Alaska.

I am pleased to be here today to once again testify before the Commerce Committee on an issue of great importance to the seafood industry. The topic of mandatory federal inspection of seafood products has been with us for many years, but recently, with the increase in publicity about seafood safety, we have seen a shift in attitude by many industry groups. Our association, for instance, has taken a position in favor of mandatory federal seafood inspection. And while this is largely the result of a desire to put a halt to the distorted view the public has been given regarding the risks of consuming seafood, the fact remains that a perception problem exists and the imposition of mandatory federal inspection may be the only way of fixing the damage which has been done caused by the negative picture the media has painted of the seafood industry.

Having said that, let me explain in more detail the position of PSPA in regard to federal seafood inspection. In general, our goal is to see a program established which will provide the consumer the same degree of confidence which is afforded by the federal inspection of meat and poultry products. More specifically, we think that the program should consist of the following points:

It should be federally funded

It should be based upon the scientifically based concept of Hazard Analysis Critical Control Point (HACCP) monitoring

It should not be continuous

It should be as stringent in its coverage of imported products as it is for domestic products

It should be under the authority of a single federal agency to minimize confusion and duplication of effort, and that agency should have the ability to delegate the inspection role to qualified states

And, specific to our region, the program should include intact the ongoing and successful "Canned Salmon Control Plan" which is currently administered by the Food and Drug Administration

The one item which PSPA has not taken a formal position on regards the choice of an agency to be in charge of this program. Opinions within the association vary on this, and we have simply not been able to reach a concensus.

The domestic seafood industry has taken quite a bit of heat during the past few years and the public health record has been badly distorted. We are disappointed that the federal government was unable to correct the misrepresentations which have been made and that public confidence in the seafood supply has been shaken. Nevertheless, if we need to accept a federal program similar to that for meat and poultry because of this situation we are ready and willing to do so on the terms and conditions I have outlined.

I would also like to take a moment to touch on some procedural questions surrounding the handling of the seafood safety issue by Congress and the Administration. The domestic seafood industry has had a positive and longstanding relationship with the Senate Commerce Committee and the House Committee on Merchant Marine and Fisheries. We feel that because of this relationship, and because of the level of expertise within these Committees regarding seafood issues generally, that any legislation dealing with seafood inspection should be given a thorough review by both these Committees before it is enacted. It is true that the jurisdiction in this case has become clouded because this issue deals not only with seafood but with public health. Nevertheless, we feel it is critical that the members of Congress who know our industry the best have a major role in crafting a bill, and we are pleased, therefore, that the Commerce Committee is conducting today's hearing and is pursuing S. 2228. We have no doubt that the final program which emerges will be better because of this Committee's involvement.

This concludes my statement. I will be pleased to answer any questions you may have.

The CHAIRMAN. Mr. Moore.

STATEMENT OF KEN MOORE, CHAIRMAN, INTERSTATE SHELLFISH SANITATION CONFERENCE, COLUMBIA, SC

Mr. MOORE. Mr. Chairman, it is certainly a pleasure to be here, first as Chairman of the ISSC and secondly as a resident of your home state. I thank you for the opportunity to share the views of the ISSC on the Consumer Seafood Safety and Quality Assurance Act of 1990.

Interstate Shellfish Sanitation Conference is an organization comprised of State regulatory officials, the shellfish industry, academia, and the following Federal agencies which share responsibility: The Food and Drug Administration is the lead agency; the National Oceanic and Atmospheric Administration; and the Environmental Protection Agency.

In addressing S. 2228, first let me commend the committee and its staff for their efforts in researching the issue and developing the proposed legislation. Mollusc shellfish are a major concern to the seafood safety issue.

In reviewing the Act I found several important elements consistent with the National Shellfish Sanitation Program which would strengthen shellfish sanitation in this country if enacted into legislation:

The Act appropriately increases Federal authority;

The Act clearly defines the term "adulterated", which would make enforcement more effective;

The Act makes State compliance mandatory;

The Act includes provisions for Federal intervention in State programs which are not in compliance;

The Act applies Federal guidelines to imported seafood products which not only promote seafood safety but creates economic quality;

The Act provides funding to State programs, probably the most important element of the bill. All states would like more comprehensive seafood safety programs but are tremendously limited by present funding. The major problems which exist today in shellfish sanitation programs are linked directly to inadequate funding;

The Act establishes civil and criminal penalties which would serve as a deterrent to those activities which contribute to unsafe seafood and seafood products;

The Act establishes programs to address research, education and, most notably, health risk monitoring. The illness data presently available is inconclusive and completely inadequate to assess present health risk.

While the ISSC strongly supports the components of this proposed legislation, we have three concerns. The ISSC endorses and supports the U.S. Food and Drug Administration as the Federal agency which should administer a Federal seafood safety program. The outstanding cooperation of the Food and Drug Administration has contributed to the success of the National Shellfish Sanitation Program and the Interstate Shellfish Sanitation Conference.

FDA's present role in shellfish sanitation is not well understood. The National Shellfish Sanitation Program does not recognize FDA as a compliance and enforcement agency. Those responsibilities are clearly directed to states. FDA's role includes training, technical assistance, and State evaluations. FDA functions well in these roles.

The second concern, the bill does not include prohibition for the harvesting of seafood from areas designated under the Act as not in compliance. Harvesting prohibitions would create a greater deterrent to illegal harvesting of shellfish which is a growing public health concern.

Third, the draft legislation states that the Secretary of Commerce in consultation with the Secretary of Agriculture and Health and Human Services will develop a comprehensive seafood safety and quality assurance program. The program is to be consistent to the maximum extent practical with the National Shellfish Sanitation Program developed by the Interstate Shellfish Sanitation Conference.

The present NSSP guidelines are the product of eight years of review and change by the Interstate Shellfish Sanitation Conference, and they represent the best knowledge and expertise that this country has to offer. This effort by the ISSC has been a successful endeavor, and this success can be attributed primarily to the participatory nature of the Interstate Shellfish Sanitation Conference process. State regulatory agencies as well as industry more readily accept guidelines when they are allowed to participate in their development. The process creates a sense of shared ownership.

The Interstate Shellfish Sanitation Conference is referenced in this Act, but its role should be more clearly defined. The major role of the Interstate Shellfish Sanitation Conference is development of national shellfish sanitation guidelines, and states dedicate resources to the organization for that purpose. If this role is eliminated, there may not be an Interstate Shellfish Sanitation Conference.

The efforts of the Interstate Shellfish Sanitation Conference have greatly improved shellfish safety, and to insure this continued progress Federal legislation should grant authority to the Interstate Shellfish Sanitation Conference to develop shellfish standards and guidelines for the comprehensive seafood safety and quality assurance program outlined in this Act.

The ISSC again thanks the committee for an opportunity to present its views.

[The statement follows:]

Statement of

Ken B. Moore, Chairman

Interstate Shellfish Sanitation Conference

Mr. Chairman:

My name is Ken Moore, Chairman of the Interstate Shellfish Sanitation Conference (ISSC), and I am pleased to have this opportunity to share the position of the ISSC on the Consumer Seafood Safety and Quality Assurance Act of 1990.

In addition to serving as the current Chairman of the ISSC, I manage the Shellfish Sanitation Program with the South Carolina Department of Health and Environmental Control. In South Carolina, all of the essential elements of shellfish sanitation including classification of harvesting areas, processing and plant sanitation, harvesting, relaying, depuration, and patrol are within one program in one agency. Additionally, I am also responsible for crab and finfish inspection programs in South Carolina. Therefore, I have a good understanding of the problems of seafood safety.

The Interstate Shellfish Sanitation Conference (ISSC)

The Interstate Shellfish Sanitation Conference, established in 1982, is a tripartite organization comprised of State regulatory officials, the shellfish industry, and the following federal agencies which share responsibility for the safety of molluscan shellfish: the Food and Drug Administration (FDA) as the lead agency, the National Oceanic and Atmospheric Administration (NOAA), and the Environmental Protection Agency (EPA). The ISSC has a formal Memorandum of Understanding with FDA to promote shellfish sanitation through the National Shellfish Sanitation Program (NSSP) which is a federal/State/industry cooperative program. The ISSC provides the forum for establishing guidelines *for the National Shellfish Sanitation Program. The ISSC proposes guidelines which, after review by the FDA, are incorporated into the NSSP guidelines. FDA then uses these guidelines in evaluating State shellfish sanitation programs. The shared regulatory development process of the NSSP has created greater cooperation among the involved parties and has resulted in substantial improvements in State shellfish sanitation programs.*

The ISSC is structured to allow open debate of issues and concerns. All issues are reviewed in committees and task forces before being presented to a voting delegation comprised of State regulatory representatives. The Conference brings together vast expertise from State and federal agencies, the shellfish industry, and the academic community to solve public health problems in the area of shellfish sanitation.

The ISSC is currently involved in several areas which have serious public health implications. These include:

(1) Vibrio vulnificus which is a serious health concern associated with a naturally occurring organism not related to pollution. It affects individuals with compromised immunity systems. The Conference has taken an educational approach designed to make high risk groups more aware of the potential dangers;

(2) Shellfish importation from foreign countries without a Memorandum of Understanding (MOU) with FDA. The MOU process is the only assurance that shellfish are harvested from non-polluted waters and handled in a sanitary manner. I conveyed this concern to all State shellfish control agencies in a letter dated July 27, 1989, a copy of which I would like to submit for the record;

(3) Aquaculture is rapidly expanding in the United States and presently the NSSP does not include guidelines to ensure proper sanitary control. To

correct this, ISSC has a committee which is currently preparing draft guidelines for Conference review and subsequent inclusion into the NSSP;

(4) The ISSC is involved in an extensive training and standardization initiative to achieve uniformity in State evaluations. The Conference recently instituted a pilot study which included the use of standardized shellfish processing plant inspection forms. The pilot study also included training for both federal and State regulatory personnel;

(5) The Conference is preparing a Model Code for State adoption which will address all shellfisn sanitation elements necessary for NSSP compliance;

(6) The ISSC actively supports research to improve shellfish sanitation, most notably the National Indicator Study which has received partial federal funding. This study will attempt to develop laboratory tests and methods which are more indicative of potential public health risk.

Tremendous progress has occurred as a result of the federal/State/industry regulatory network involved in the present FDA cooperative program.

At the Annual Meeting of the ISSC in July 1989, with 32 states represented, two resolutions were adopted without opposition which address the issue of federal responsibility for seafood safety. Resolution 89-3, submitted by an industry trade association, recognizes and endorses the continued efforts of the Food and Drug Administration and the current National Shellfish Sanitation Program, through the ISSC, in regulating the shellfish industry.

The Conference also adopted Resolution 89-4, which more specifically expresses the ISSC position supporting congressional appropriation of significant additional resources to the existing federal programs in the Food and Drug Administration, National Marine Fisheries Service, and the Environmental Protection Agency. Such action is necessary to meet increasing public health and product quality demands and assure a continuing adequate *supply of safe and high quality domestic and imported fish and shellfish. I would like to submit copies of both resolutions for the record.*

The ISSC recognizes the important role of FDA in public health protection. The outstanding cooperation of FDA has been a key ingredient in the success of the NSSP. The NSSP is a preventative public health plan. FDA provides highly skilled technical expertise in the complex areas of bacterial analysis, hydrographics, sanitary surveys, and engineering. This type of expertise is difficult to obtain.

Additionally, FDA provides assistance to States and industry by conducting training seminars for shellfish industry and State regulatory personnel. Administrative guidance is also provided to states which are establishing new shellfish sanitation program elements.

Consumer Seafood Safety and Quality Assurance Act of 1990

I would like to commend the staffs of the Committee on Commerce, Science, and Transportation who participated in the development of this legislation. The draft bill appropriately addresses every important element in the aspect of seafood safety in an appropriate manner. In reviewing the Act, I found important elements consistent with the NSSP which would strengthen shellfish sanitation in this country if enacted into federal regulation.

(1) The establishment of a new comprehensive seafood safety and quality assurance program consistent with ISSC guidelines is mandated by this draft legislation. This additional legislation is needed to give the designated federal agency more authority to adequately regulate the safety of seafood products.

(2) Section 3 defines "adulterated" in very specific terms and Section 6(e) clearly provides authority to condemn and destroy seafood deemed

adulterated. In existing federal law, "adulteration" is defined in a manner which often makes seizure and condemnation difficult.

(3) *The Act makes State compliance with federal guidelines mandatory and also provides sanctions which may be imposed upon non-complying states. The present cooperative program has been outstanding in evaluating State programs and making progressive recommendations, yet it is not structured to address imminent health concerns associated with seafood products.*

(4) *This proposed legislation includes federal intervention and the circumstances under which it would be incorporated. Although intervention is a necessary component, it must be structured in a manner that will be supported by States. Presently the ISSC has a structured forum for addressing unresolved issues between parties. This forum could be expanded to review situations in which federal intervention in State programs may be necessary.*

(5) *This Act applies federal guidelines to imported seafood and seafood products which not only enhances seafood safety but creates economic equality by requiring that all seafood products, foreign and domestic, be subjected to the same regulatory scrutiny.*

(6) *Most importantly the Act provides funding to States which choose to implement the established program. Lack of funding has long been recognized as the single greatest problem encountered by States in implementing adequate seafood safety programs. Appropriate funding of State programs would greatly improve all elements of seafood safety, most notably illegal harvesting from prohibited areas.*

(7) *Section 11 of the proposed legislation establishes civil and criminal penalties for persons violating provisions of the Act. These penalties will serve as a deterrent for those activities which can contribute to an*

unsafe seafood product such as improper handling and transportation, and mislabeling.

(8) Sections 14 and 15 of the Act establish programs to address research, education, and health risk monitoring where greater attention is needed to enhance seafood safety. As stated earlier, the Act particularly recognizes a lack of adequate health risk monitoring. Much of the information presently being used to assess seafood related illnesses is inadequate which makes reliable assessment difficult. A clearly defined and well implemented illness reporting program would provide this much needed information. The ISSC is actively involved in a National Indicator Study to develop better laboratory tests and methods of assessing human health risks. Educational programs are needed to promote the positive aspects of seafood consumption and to alert high risk groups concerning dangers which may affect them.

Concerns

(1) Section 7(a), Monitoring System, and Section 11, Prohibited Acts, do not include prohibition of the harvesting of seafood from areas designated under the Act as not in compliance. Harvesting prohibition would create a greater deterrent to illegal harvesting which is a growing public health concern.

(2) Section 4 of the draft legislation states the Secretary of Commerce in consultation with the Secretary of Agriculture and Secretary of Health and Human Services shall develop a comprehensive seafood safety and quality assurance program. The program is to be consistent, to the maximum extent practicable, with the National Shellfish Sanitation Program developed by the Interstate Shellfish Sanitation Conference. The present NSSP is the

product of eight years of review and change by the ISSC. This effort by the ISSC has been a successful endeavor, expanding beyond the expectations of those initially involved and this success can be attributed primarily to the participatory nature of this process. State regulatory agencies as well as industry more readily accept guidelines when they are allowed to participate in their development. The process creates a sense of shared ownership of the guideline. The ISSC provides a bridge between industry and regulators resulting in more open dialogue and closer cooperation in solving problems. This participatory approach involving industry and government has been highly successful and will result in continued success in improving shellfish sanitation and protection of public health. The Interstate Shellfish Sanitation Conference is referenced in this Act but its role should be more clearly defined. The efforts of the ISSC have greatly improved shellfish safety and to ensure this continued progress, federal legislation should grant authority to the Interstate Shellfish Sanitation Conference to develop shellfish sanitation standards and guidelines for the comprehensive seafood safety and quality assurance program outlined in this Act.

The CHAIRMAN. Well, we are indebted to you, Mr. Moore, and Mr. Iani.

Ms. Bloom, I am trying to make a composite judgment in my own mind of the necessary elements of the legislation. As I take it, we definitely need to have a harvesting provision, definitely have a whistlebower provision, and I hope the staff will take note. I may seem like a pollster, but the majority vote appears to come down on the side of the FDA if you consider the administration-weighted vote in this instance. FDA has a major part of the program now. They also have the lead responsibility, although they rely on the expertise of the National Marine Fisheries Service.

Even though you have misgivings, Ms. Bloom, about the FDA, you still say stick with the FDA because it is a health issue and not an issue of promoting commerce nor agricultural products. That is a sound position because when you get in both the promotion end and the regulatory end they become fused and confused.

Why did they leave the whistleblower provision out of the Mitchell Bill? Do you know from the Committee proceedings and so forth? There must have been strong opposition to strike it. I cannot understand it.

Ms. BLOOM. I hope I am correct on this. As I understood it, most of the opposition was coming from the meat and poultry industry which was concerned about the precedent setting effect it would have for its industry.

The CHAIRMAN. So it was not from seafood.

How about it, Mr. Moore? Would you object to a whistleblowing provision?

Mr. MOORE. I do not think the participating states of the ISSC or its members would. However, this is an issue that the ISSC has not specifically addressed.

The CHAIRMAN. How about it, Mr. Iani?

Mr. IANI. Well, in the case of our companies I do not think a whistleblower provision makes a lot of sense. Our companies operate on a seasonal basis and concentrate their processing in a few months of the year. They haul in a bunch of people, and then they are gone. It does not seem to make much sense for our companies.

The CHAIRMAN. I am trying to get the logic of why having a seasonal operation as you describe it would conflict with having a whistleblower provision. I mean, we have a whistleblower for all seasons.

Mr. IANI. Yes, I understand.

The CHAIRMAN. What is wrong with having one, then, during your season?

Mr. IANI. I have no formal objection to it. I am just wondering how it is going to work when you have a plant that operates for, oh, maybe six weeks out of the entire year.

The CHAIRMAN. Normally, of course, it would be somebody within your employ and who sees these faulty practices engaged in and blows the whistle on it.

Mr. IANI. Right, but also, Senator Hollings, because that plant can only work for six weeks and the fish are only there for six weeks, should that whistleblower provision be fraudulently used that plant would be shut down and the fish would be gone.

The CHAIRMAN. No, we would have a careful whistleblower. We have a tough time even with the whistleblowers. It is just so that you do not have punitive measures against them. Just because there is a dissident employee, you cannot have the power to close the plant down. No, it would have to be a careful provision whereby he would be heard but not necessarily, *ipso facto* he blew the whistle, that the plant was closed. We have a tough enough time with keeping him employed. This is really the protection that he needs, to be heard and not lose his job if he really brings to the public's attention wrong practices or violations.

The Shellfish Sanitation Program, Mr. Moore, is working now as you see it? The great danger is not from the Pacific catches. It would be more in your shellfish and my shellfish, bad oysters, bad clams and those kind of things.

Mr. MOORE. As I mentioned earlier, there are some problems out there. I would be naive to believe I could convince you otherwise. The problems are the result of inadequate funding. We have a very comprehensive set of guidelines. Mr. Chairman, and these guidelines cover shellfish, from the waters they grow to the consumer's plate.

The CHAIRMAN. I know fishermen, as do you. How many have read the guidelines?

Mr. MOORE. You would be surprised. In our state with some of the enforcement action that we have taken lately, there is quite a few that are very familiar with them.

The problem that we are seeing in this country in shellfish sanitation is that State programs simply do not have the funding to implement these guidelines.

The **Chairman**. So properly implemented, there is nothing wrong with the guidelines?

Mr. **Moore**. Nothing whatsoever.

The **Chairman**. All across the board we see that, whether it is in Food and Drug or wherever. Important federal programs have been totally underfunded, and we are lucky to be coming out of it. I guess we are surviving and do not have a crisis because of the states more than anything else.

Mr. **Moore**. I would agree.

The **Chairman**. Is there anything that any of the three of you wish to add? We have another vote coming up, and I have to go do some work on it.

Mr. **Moore**. I would like to add one thing even though it is not a part of this legislation. In response the discussion of user fees this morning, the Interstate Shellfish Sanitation Conference does not endorse user fees in the shellfish industry. The shellfish industry already is facing declining harvesting acreages due to pollution problems, and to incur an additional cost on them would, I think, would be terribly unfair.

The **Chairman**. Mr. Iani, do you have anything?

Mr. **Iani**. No, Senator Hollings. I appreciate the opportunity to be here, though. Thank you.

The **Chairman**. We appreciate your being here. I do not want to hold you any longer because Senator Stevens and all of us have to go to the vote. Earlier, he talked about the majority of fish coming out of the Pacific and Alaska. That is our trouble. When we order an Alaskan salmon now they do not ask you whether you want it fried or broiled. They ask you whether you want it regular or high test.

That is one of the reasons we have some momentum for this bill.

Ms. Bloom, do you have anything to add?

Ms. **Bloom**. Just on the user fee issue, we also would support a Federally funded program as far as the safety concerns go. We do not support user fees.

The **Chairman**. Very good. We appreciate your presentations here and your patience this morning. The other panel took a much longer time, but it is a very valuable presentation that each of you made. We thank you.

The Committee will be adjourned subject to the call of the Chair.

[Whereupon, at 11:41 a.m. the hearing was adjourned.]

○